STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

CHAPTER I

RELATIONSHIP WITH OTHER AGENCIES

COMMENT: Presbyterian Healthcare (23) recommended that the following wording from the 2004-2005 Plan be re-inserted into Chapter I:

> The Department is conscious that the ultimate responsibility for administering this program cannot be shared with any individual or organization; however, it does recognize the valuable contributions that can be made by other interested organizations and individuals. For that reason it will be the policy to actively seek cooperation and guidance from anyone who wishes to comment on this plan.

STAFF RESPONSE: This was part of a larger section that attempted to list all the agencies and entities consulted during the process of developing the Plan, which was deleted in the current Draft Plan. Staff recommends incorporating this wording under the previously used heading and adjusting the remaining section lettering accordingly.

H. RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA (I-3)

COMMENT: Presbyterian Healthcare (23) recommended that the following wording from the 2004-2005 Plan be re-inserted into the beginning of this section:

> **In accordance with the latest revisions to the Certification of Need and Health Facility Licensure Act**, a ~~A~~ general statement has been added to each section of Chapter II stating the project review criteria considered to be the most...

STAFF RESPONSE: This statement is no longer strictly accurate, because the CON law has been subsequently revised since this requirement was added in the previous revision. The statement was deleted as extraneous and no change is recommended.

J. SAFETY OF PATIENT CARE (I-4)

COMMENT: The SC Medical Association (1) and the South Carolina Department of Health and Human Services (37) noted a typo of "CMA" rather than "CMS" in the 2nd sentence in this section.

STAFF RESPONSE: This was corrected.

COMMENT: Lynn Bailey (5) recommended that quality and patient safety should receive greater emphasis in the Plan and the CON review process. There is publicly available data through sites like mySChospital.org that can be used. Providers with mediocre quality indicators should not be allowed to expand any of their services or be given standing to challenge other providers.

STAFF RESPONSE: The only question in the CON application that references quality of care focuses more on improved service organization (economies of design etc.) than on the actual provision of care. Staff agrees that additional emphasis can be placed on quality and patient safety issues in the planning and review processes. However, her proposals to change the interpretation of "unnecessary duplication," prohibiting providers from expanding services, and denying providers "affected person" status are not supported by current statute and cannot be supported. There are voluntary data systems that allow hospital performance comparisons against benchmarks for some quality measures such as surgical infection prevention procedures. Additional comparison measures are under development. These hospital data systems are not applicable for specialty hospitals (psychiatric, rehabilitation) or freestanding facilities, and they currently do not include benchmarks that would be specifically appropriate for all services in the Plan (i.e. there are no benchmarks in the mySChospitals.com database directly applicable for radiation therapy). Staff recommends that the following wording should be added as a new Criteria (j) on page II-9 and the remaining criteria re-alphabetized:

> Through the use of benchmark data from mySChospitals.com, hospitalcompare.hhs.gov, leapfroggroup.org, or other sources, the applicant will document how its quality of care on the available measures compares to state, regional, or national averages.

Another issue for the Committee to consider is to recommend participation in applicable data registries. Participating organizations collect and share their data to establish best practices. These collaborative efforts lead to better outcomes by reducing complications and resultant mortality. A recent study suggested that around 300 hospitals in the U.S. are providing Emergent PCI without Open Heart backup, but only about 100 participate in a registry that could provide data to ensure good quality control and improve outcomes. We currently require Radiation Therapy providers to operate their own tumor registry or participate in a central tumor registry. We could add a requirement in the Plan that an applicant must agree to share their outcomes data with an appropriate registry where applicable.

LABOR RESOURCES

COMMENT: Lynn Bailey (5) requested that the Planning Committee undertake a study to determine how best to incorporate nursing and technical staffing information into future Plans. Currently, at the same time there are major facility expansions occurring there is a shortage of key labor resources. The quality and quantity of staffing are linked to the quality and safety of care.

STAFF RESPONSE: Staff is not opposed to undertaking such a study.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

A. GENERAL HOSPITALS (II-4-19)

COMMENT: SCHA (12) commented that the populations of counties that do not have hospitals are never factored into the bed need projections for hospitals unless they are combined into a service area. They requested that DHEC staff develop a methodology in a future Plan for calculating and accounting for their impact.

STAFF RESPONSE: The current methodology does not incorporate the populations of Saluda, McCormick, and Lee Counties into the bed need projections. The Regional Medical Center is designated to serve both Orangeburg and Calhoun Counties, so their populations are merged. Berkeley County is incorporated into the Berkeley/ Charleston/Dorchester service area. Staff agrees to address this issue in the next Plan.

COMMENT: Georgetown Hospital System (10) supported maintaining the current bed need methodology.

COMMENT: Carolinas HealthCare System (21) supported the methodology allowing any entity to apply for additional beds when there is an overall need for additional beds in a county.

COMMENT: Palmetto Health (19) agreed with the bed need methodology being based on individual hospital utilization. However, they suggested that other hospitals should not be allowed to apply for beds shown as needed by an individual hospital without that facility's consent, because capital plans may not allow the facility to apply for those beds until subsequent years.

STAFF RESPONSE: Staff does not believe such a requirement is feasible.

COMMENT: Roper St. Francis (4) recommended that all multiple county metropolitan areas be treated the same regarding hospital bed need.

STAFF RESPONSE: Staff recommends addressing this issue when revising the bed need methodology as previously requested by SCHA (12).

COMMENT: Presbyterian Healthcare (23) stated that Standards 4D and 4E on page II-7 are mutually exclusive.

STAFF RESPONSE: This is intentional. Standard 4D applies when there is an overall surplus of beds in a particular county; Standard 4E applies when there is an overall need for additional beds in a county. These standards were incorporated to address how the Department would review the different scenarios that can result from the bed need methodology.

COMMENT: Spartanburg Regional (20) supported the reduction in the number of beds that can be added to form an economical unit from 50 to 30 beds (Standards 4D and 4E on page II-7).

COMMENT: Presbyterian Healthcare (23) opposed the reduction in the number of beds that can be added to form an economical unit from 50 to 30 beds (Standards 4D and 4E on page II-7), citing their experience with their 50 bed hospital in Huntersville, NC.

COMMENT: Loris Healthcare System (26) opposed the reduction in the number of beds that can be added from 50 to 30 beds to meet future needs without additional construction or renovation. They proposed amending Standard 4D back to 50 beds.

COMMENT: Bon Secours St. Francis (24) stated that the proposed reduction from 50 to 30 beds is accurate for the expansion of existing buildings; it is not economically efficient for new construction of satellite hospitals. If a facility has a calculated need for more than 30 beds and is planning a satellite hospital, the facility should be allowed to add a minimum of 50 beds.

COMMENT: SCHA (12) proposed the following amendment to Standard 4D on page II-7:

> If a county indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the county indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to 30 additional beds may be approved for that hospital to allow for the construction of an economical unit at ~~either~~ the existing hospital site ~~or another site,~~ **as part of an expansion or renovation project. I**~~i~~f the existing hospital is relocating or has relocated in whole or in part to **another** ~~that~~ site, **then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical satellite hospital at that site.** The hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

COMMENT: Bon Secours St. Francis (24) proposed the following amendment to Standard 4D:

> If a county indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the county indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to **50** additional beds may be approved for that hospital to allow for the construction of an economical **satellite hospital** ~~unit~~ at either the existing hospital site or another site, if the existing hospital is

relocating or has relocated in whole or in part to that site. **For expansion of current buildings where an individual hospital indicates a need for additional beds, then a maximum of the actual projected bed need or up to 30 additional beds may be approved for that hospital or any other hospital within the same hospital system to allow for expansion construction of existing buildings at that existing hospital site or any site within the same hospital system. In either case, t**~~T~~he hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

STAFF RESPONSE: It appears that there is interest in both the development of additional facilities and the expansion of existing ones. The majority of the respondents favored either: 1) returning to the previous 50 bed standard; or 2) keeping the standard at 30 beds for expansion of an existing hospital but allowing a new facility to construct up to 50 beds for economies of scale in construction. Based on these comments, staff recommends accepting the SCHA (12) amendment to Standard 4D on page II-7:

If a county indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the county indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to 30 additional beds may be approved for that hospital to allow for the construction of an economical unit at ~~either~~ the existing hospital site ~~or another site,~~ **as part of an expansion or renovation project. I**~~i~~**f** the existing hospital is relocating or has relocated in whole or in part to **another** ~~that~~ site, **then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical satellite hospital at that site**. The hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

COMMENT: Presbyterian Healthcare (23) proposed the following amendment to the first sentence of Standard 4E on page II-7:

If there is a need for additional hospital beds in the county, then any entity may apply to add these beds within the county**, and any entity may be awarded the Certificate of Need for these beds.**

STAFF RESPONSE: Staff recommends accepting this comment.

COMMENT: Loris Healthcare System (26) proposed amending Standard 4E on page II-7 back from 30 to 50 beds.

COMMENT: Bon Secours St. Francis (24) proposed the following amendment to Standard 4E on page II-7:

> If there is a need for additional hospital beds in the county, then any entity may apply to add these beds within the county. If the number of beds needed is less than **50**, than up to a total of **50** beds could be approved for any ***(sic.)*** **for a** ***(sic.)*** **construction of a satellite hospital at any location within the county** ~~entity at any location within the county~~. **If the number of beds needed is less than 30, then up to a total of 30 beds could be approved for the expansion of any existing hospital building within the county.** An applicant requesting additional beds beyond those indicated as needed by the methodology stated above, must document the need for additional beds based on historical and projected utilization, floor plan layouts, projected population growth that has not been considered in this Plan or other factors demonstrating the need for the proposed beds. It is up to the applicant to document the need and the potential negative impact on the existing facilities.

STAFF RESPONSE: Staff proposes that Statement 4E on page II-7 be amended as follows:

> If there is a need for additional hospital beds in the county, then any entity may apply to add these beds within the county, **and any entity may be awarded the Certificate of Need for these beds**. If the number of beds needed is less than 30, than up to a total of 30 beds could be approved ~~for any entity at any location within the county~~ **to allow for the construction of an economical unit at an existing hospital site as part of an expansion or renovation project. If the applicant hospital is relocating or has relocated in whole or in part to another site, then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical satellite hospital at that site.** An applicant requesting additional beds beyond those indicated as needed by the methodology stated above, must document the need for additional beds based on historical and projected utilization, floor plan layouts, projected population growth that has not been considered in this Plan or other factors demonstrating the need for the proposed beds. It is up to the applicant to document the need and the potential negative impact on the existing facilities.

COMMENT: Roper St. Francis (4) and Georgetown Hospital System (10) proposed that any new hospital approved under Standard 4 must be a general hospital, that operates at least a Level III ER, accepts all government reimbursement, and provides indigent care. Palmetto Health (19) recommended that any new hospital must meet minimum service criteria, accept Medicare and Medicaid and have an indigent care policy that is consistent with the community. Spartanburg Regional (20) recommended that any new hospital

approved must be a general hospital with at least a Level III ER. SCHA (12) provided a more specific recommendation for a new Criterion in the bed need calculations:

> No additional hospitals will be approved unless they are a general hospital and will provide:
>
> 1. A 24-hour emergency services department, and meets the requirements to be a Level III emergency service as defined in Regulation 61-16 Sec. 613 Emergency Services.
> 2. Inpatient medical services to both surgical and non-surgical patients, and
> 3. Medical and surgical services on a daily basis within at least 6 of the major diagnostic categories as recognized by Centers for Medicare and Medicaid Services (CMS), as follows:
>
> MDC 1: Diseases and disorders of the nervous system
> MDC 2: Diseases and disorders of the eye
> MDC 3: Diseases and disorders of the ear, nose, mouth and throat
> MDC 4: Diseases and disorders of the respiratory system
> MDC 5: Diseases and disorders of the circulatory system
> MDC 6: Diseases and disorders of the digestive system
> MDC 7: Diseases and disorders of the hepatobiliary system and pancreas
> MDC 8: Diseases and disorders of the muscoskeletal system and connective tissue
> MDC 9: Diseases and disorders of the skin, subcutaneous tissue and breast
> MDC 10: Endocrine, nutritional and metabolic diseases and disorders
> MDC 11: Diseases and disorders of the kidney and urinary tract
> MDC 12: Diseases and disorders of the male reproductive system
> MDC 13: Diseases and disorders of the female reproductive system
> MDC 14: Pregnancy, childbirth and the puerperium
> MDC 15: Newborns/other neonates with conditions originating in the prenatal period
> MDC 16: Diseases and disorders of the blood and blood-forming organs and immunological disorders
> MDC 17: Myeloproliferative diseases and disorders and poorly differentiated neoplasms
> MDC 18: Infectious and parasitic diseases
> MDC 19: Mental diseases and disorders
> MDC 20: Alcohol/drug use and alcohol/drug-induced organic mental disorders
> MDC 21: Injury, poisoning and toxic effects of drugs
> MDC 22: Burns
> MDC 23: Factors influencing health status and other contact with health services
> MDC 24: Multiple significant traumas.
> MDC 25: Human immunodeficiency virus infections

Any applicant for a new hospital must provide a written commitment that the facility will accept Medicare and Medicaid patients, and that un-reimbursed services for indigent and charity patients are provided at a percentage which meets or exceeds other hospitals in the service area.

COMMENT: Carolinas HealthCare System (21) proposed similar standards as SCHA, with the difference being a requirement for a daily minimum of 5 CMS categories versus the 6 in the SCHA proposed language.

STAFF RESPONSE: Staff has no objection to the concepts of requiring emergency services, accepting indigent care, and providing inpatient services as requirements for the establishment of a new hospital. Staff recommends that the SCHA recommendation cited above be incorporated as a new Section (f) in the bed need methodology on page II-8 and the remaining sections be re-alphabetized.

STAFF COMMENT: Because the LTCH facilities have been removed from the inventory and bed need calculations, the Hospital Occupancy Rates table on page II-20 has been revised to exclude these facilities from the regional calculations. The LTCH occupancy will be incorporated into the LTCH section of the Draft Plan.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

B. LONG TERM ACUTE CARE HOSPITALS (II-21-23)

STAFF COMMENT: Staff recommends replacing all references to "Long Term Care Hospitals" with "Long Term Acute Care Hospitals," and all references to "LTHC" with "LTAC" to correspond with the actual federal designations for these facilities.

STAFF COMMENT: As stated in the General Hospital comments, staff recommends removing the LTCH utilization from the General Hospital Occupancy Rates table on page II-20 and incorporating the past 3 years of LTCH occupancy rates into this section. The current Draft only lists the number of beds and 2006 occupancy for each facility on page II-22. This new data table would replace the listing of the 7 facilities on that page.

STAFF COMMENT: Staff recommends that the following be added to the last sentence of the 1st paragraph on page II-21 for information purposes:

> Medicare pays for about 73% of all LTA~~H~~C discharges**; the proposed standard federal reimbursement for 2009 is $39,076 per patient.**

COMMENT: Bon Secours St. Francis (24) proposed the following amendment to Standard 2 on page II-22:

> Although Long Term Hospital beds are not considered to be a separate category for licensing purposes, they will be inventoried separately from general acute care hospital beds for planning purposes. **A hospital that has leased general beds to a Long Term Care Hospital shall be entitled to regain these beds once the lease is terminated according to the following procedure:**
>
> **(a) the hospital shall seek a Certificate of Need to regain the beds;**
>
> **(b) the hospital shall not be required to show a need for the beds under the bed need methodology set forth at pages II-6 through II-19;**
>
> **(c) the Certificate of Need shall be granted upon a showing by the hospital that the lease has terminated and that the hospital has a use for those beds without regard to the bed need methodology set forth at pages II-6 through II-19;**
>
> **(d) upon receipt of the Certificate of Need, the beds shall be re-licensed to the hospital. No entity other than the hospital which initially leased the general acute beds (or its successor) to the Long Term Care Hospital shall be entitled to obtain the rights to the beds upon termination of the lease.**

STAFF RESPONSE: Staff does not recommend incorporating these changes in Standard 2. Instead, staff believes it is more appropriate to address these proposed revisions in the discussion of Standard 4 revisions below.

COMMENT: Palmetto Health (19) recommended that that Standard 4 on page II-22 be revised to require that a bed need must exist in the service area before LTCH beds could be converted to general acute beds.

STAFF RESPONSE: This is not consistent with other standards in the Plan, such as Standard 4H2 (II-8) that allows beds to be converted regardless of whether there is a projected need as long as a CON is obtained. Staff does not recommend accepting this comment.

COMMENT: Georgetown (10), SCHA (12), and Spartanburg Regional (20) recommended that Standard 4 be revised as follows:

> A Certificate of Need is required to convert LTCH beds to general acute care hospital beds**, rehab beds, or psych beds**.

STAFF RESPONSE: Staff agrees with the sentiment of the recommendation and has incorporated it into the proposed revisions below.

COMMENT: Georgetown (10) and SCHA (12) recommended the following additional standard. Spartanburg Regional (20) proposed a similar standard:

> An acute care hospital, which has been awarded a CON to convert acute care beds for use in creating an LTAC, may again use its beds for acute care regardless of bed need within the county. If it is unable to acquire CMS certification as an LTAC, or if it no longer wishes to operate as an LTAC at that time, the hospitals beds will revert back to the official inventory of beds within that hospital.

STAFF RESPONSE: Staff believes that Standard 4 is the more appropriate location to address both the Georgetown *et. al.* comments and the amendments that Bon Secours St. Francis (24) proposed to Standard 2 on page II-22. Staff cannot support the Georgetown *et. al.* proposal as written. The acute hospital isn't awarded the CON to convert their beds. It is awarded to the LTAC, which must have a different license, management, etc. Once a hospital leases or sells their beds for an LTAC they technically don't "belong" to that facility anymore; therefore they cannot just revert back to the acute hospital's bed inventory. Such a bed conversion would require a CON. In other sections we allow the conversion from specialty to general acute beds regardless of the bed need, and staff recommends that this apply here as well. However, since the previous Georgetown (10) comment references conversion to rehab and psych beds, staff believes that it should be stated that conversion to these specialty beds will not be approved unless there is a projected need for these beds in the appropriate service area. Staff also agrees with the sentiment in the Bon Secours St. Francis (24) proposal that no other entity should have a right to these beds. Staff proposes the following revision to Standard 4 on page II-22:

(4) ~~A Certificate of Need is required to convert LTCH beds to general acute care hospital beds~~. **A hospital that has leased general beds to a Long Term Care Hospital shall be entitled to regain these beds once the lease is terminated. No entity other than the hospital that initially leased the general acute beds (or its successor) to the Long Term Care Hospital shall be entitled to obtain the rights to the beds upon termination of the lease. A Certificate of Need application is required:**

(a) a hospital may be allowed to convert these former LTAC beds to general acute hospital beds regardless of the projected need for general acute beds;

(b) a hospital may only be allowed to convert these former LTAC beds to psychiatric, inpatient treatment facility, rehabilitation, or other specialty beds if there is a bed need projected for this proposed other category of licensed beds.

COMMENT: Georgetown (10) and SCHA (12) recommended the following additional standard. Spartanburg Regional (20) proposed a more general standard:

> A hospital which desires to be designated as an LTAC and has been awarded a CON for that purpose, must be certified as an LTAC by CMS within 24 months of accepting its first patient, or the CON issued to that hospital for that purpose shall be revoked. That entity which has had its CON revoked shall not have the authority to operate as a general acute care hospital.

STAFF RESPONSE: This recommendation has been discussed with the DHEC Legal staff. It is their opinion that such a requirement can be made as a condition of CON approval. Therefore, staff recommends accepting this recommendation with a slight grammatical correction as a new Standard 5 on page II-22:

> A hospital which desires to be designated as an LTAC and has been awarded a CON for that purpose, must be certified as an LTAC by CMS within 24 months of accepting its first patient, or the CON issued to that hospital for that purpose shall be revoked. That entity **that** ~~which~~ has had its CON revoked shall not have the authority to operate as a general acute care hospital.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

C. CRITICAL ACCESS HOSPITALS (II-24-25)

STAFF COMMENTS: The following revisions were not precipitated by comment received during the public comment period. However, because they involve revisions to bring this section current with federal guidelines, they are included as staff recommended changes. Staff recommends the following revision to Standard 1 on page II-24:

(1) It must be located in a rural county. It may be either an existing facility or a hospital that closed or downsized to a health center or clinic after November 29, 1989. **A facility may be allowed to relocate or rebuild provided it meets the CMS criteria.**

States are no longer allowed to qualify hospitals for CAH status by certifying them as being necessary providers of health care services to residents of an area, although currently certified facilities have been grandfathered. As a result, staff proposes the following revision to Standard 3 on page II-24:

(3) The facility must be located more than 35 miles from any other hospital or CAH (15 miles for areas with only secondary roads) or **must have** been certified by the State **prior to January 1, 2006** as being a necessary provider of health care services to residents of the area;

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

D. OBSTETRICAL AND NEONATAL SERVICES (II-26-36)

COMMENT: Palmetto Health (19) acknowledged the importance of the current regional network. Because of the staff, equipment, and consultative services required, they recommended that preference be given to established providers where a need for additional Level III bassinets exists.

STAFF RESPONSE: Staff concurs that the existing regional network should be supported.

COMMENT: Presbyterian Healthcare (23) recommended that a deleted statement requiring licensure and JCAHO accreditation be re-added to page II-30.

STAFF RESPONSE: The statement was deleted because a hospital must be licensed in order to operate and JCAHO (now TJC) accreditation is voluntary. Staff does not recommend any changes.

COMMENT: Presbyterian Healthcare (23) recommended that the following deleted statement from the 2004-2005 Plan be added back:

> The existing bassinets in the preceding table and the table below are based on the number stated on the hospital license or approved under the Certificate of Need program.

STAFF RESPONSE: This statement was deemed redundant and deleted, since all of the bed inventories in the Plan are based on either licensed or CON-approved beds. No change is recommended.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

F. CARDIOVASCULAR CARE (II-38-58)

COMMENT: MUSC (28) commented that the utilization standards [**Note**: "Diagnostic Equivalents" on page II-41] do not adequately account for pediatric cardiac catheterizations. Issues include small patient size, increased use of anesthesia, and complex abnormal anatomy and hemodynamics. They recommended a number of revisions to the calculations for pediatric cath lab utilization. First, they proposed that pediatric diagnostic caths continue to be weighted as 2 equivalents but that therapeutic caths be weighted as 3 equivalents. Second, an electrophysiology (EP) study for a pediatric patient often requires a diagnostic cath, so EP studies should be weighted as 3 equivalents and counted as a cath procedure. Also, biopsies performed after heart transplants have to be performed in a cath lab and often require hemodynamic monitoring, so they should also be included in the cath lab utilization.

After staff held telephone discussions with MUSC physicians and administrators to clarify their comments, MUSC submitted a more detailed proposal including the specific ICD-9 codes to be used for data calculation purposes.

STAFF RESPONSE: We measure the capacity of cardiac cath labs in terms of diagnostic equivalents. Therapeutic procedures are weighted higher than diagnostic because they require more time in the cath lab. MUSC is the only facility in the state that performs pediatric cardiac catheterizations, which are presently weighted as 2 diagnostic equivalents, regardless of whether they are diagnostic or therapeutic when calculating cath lab capacity.

Their first proposal was to continue to weight pediatric diagnostic caths as 2 equivalents but to increase the weight of therapeutic caths to 3 equivalents. The Joint Annual Report (JAR) for Hospitals is already formatted for pediatric diagnostic and therapeutic cath data to be reported separately, so this will require no additional staff effort for data compilation. Staff does not object to this proposal.

Their second proposal to count EP studies as 3 equivalents, as well as counting them as a cardiac cath procedure, was amended after the telephone discussions. MUSC is now requesting that EP studies be counted as 2 equivalents when calculating utilization but does not request that they be counted as cardiac cath procedures. They would continue to be reported under "All Other" on the JAR and MUSC would assume responsibility for delineating the number of EP studies done for utilization calculations. Since MUSC has provided the specific ICD-9 codes to be used and would be responsible for reporting the data correctly, staff recommends accepting this proposal.

MUSC also proposed to count biopsies performed after heart transplants as 1 equivalent since these also have to be performed in the cath lab. Like the EP proposal above, they would continue to be reported under "All Other" on the JAR and the number of biopsies

performed then separately reported to the Department for calculating utilization. Staff recommends accepting this proposal.

COMMENT: MUSC (28) provided a copy of an ACC/AHA task force report on the organization of delivery systems for Adults with Congenital Heart Disease (ACHD), focusing on the definition of a catheterization laboratory. They indicated that MUSC has been performing these procedures on adults in the pediatric cath lab and that this utilization should be counted in the pediatric lab utilization. They later submitted a more detailed proposal for adult concomitant congenital heart disease procedures to be counted in what they request be renamed a "Pediatric and Adult Congenital Cath Lab," including the relevant ICD-9 codes.

STAFF RESPONSE: MUSC has 5 adult cath labs plus the pediatric cath lab. These adult patients (approximately 66 in 2006 and 56 in 2007) have been treated in the pediatric cath lab, but they were reported in the adult lab numbers. Because it would more accurately reflect the actual utilization of the pediatric lab, MUSC requested to report these procedures where they are actually being provided. It does not appear that such a request would significantly impact either MUSC's adult numbers or those of the surrounding service area. The Greater Charleston service area already does not show the need for an additional cardiac cath provider, so this change would not impact the ability of a new provider to apply to establish services. However, it makes a significant impact on the calculated utilization of the pediatric lab.

COMMENT: During the discussions with MUSC, they determined that they had under-reported their adult and pediatric cath lab utilization for 2006. During this time period, if a patient was hospitalized and cath lab procedures occurred on multiple dates during the hospital stay, these cases were only counted once instead of being counted separately for each occurrence. MUSC submitted revised data and also provided a breakout showing what the impact of the proposed revisions would be.

STAFF RESPONSE: If the Committee does not accept the proposed revisions to the cath lab methodologies, MUSC's 2006 utilization would be as follows:

Adult Diagnostic	1,822
Adult Therapeutic	780
Total Equivalents	3,382
Equivalents/Lab	676.4

Pediatric Caths	322
Total Equivalents	644
Equivalents/Lab	644.0

Accepting all of the MUSC recommended revisions would result in the following:

Adult Diagnostic	1,802
Adult Therapeutic	734

Total Equivalents	3,270
Equivalents/Lab	654.0
Ped Diagnostic	181
Adult Cong Diag	20
Ped Therapeutic	141
Adult Cong Ther	46
Ped EP	77
Adult Cong EP	1
Ped Biopsies	10
Total Equivalents	1,130
Equivalents/Lab	1,130

COMMENT: Richard Baehr (17) stated that the current Plan standards limiting PCI to hospitals with open heart surgery, except for tightly defined emergency situations, means that the treatment may not be available in all cases when patients present to hospital emergency rooms.

STAFF RESPONSE: Staff agrees that the treatment may not be immediately available in all cases, which is why there are transfer agreements with the appropriate providers. It has never been suggested that every hospital ER should have emergent PCI capability.

COMMENT: Providence Hospital (13) supports Standard 8 on pages II-43-45 allowing hospitals to offer emergent PCI without open heart backup provided they meet the ACC/AHA guidelines.

STAFF RESPONSE: None required.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

C-PORT PROVISION (II-49)

NOTE: BECAUSE OF THE NUMEROUS CHANGES TO THIS SECTION, A PROPOSED REVISED VERSION OF THIS SECTION IS ATTACHED

COMMENT: Georgetown (10 and 27) supported the Plan allowing participation in the C-PORT study (Standard 9 on page II-45).

COMMENT: Richard Baehr (17) noted that a number of states are participating in the C-PORT study and that PCI without open heart backup is already performed in states without CON programs. He also stated that recent research has shown that physician proficiency and quality of clinical staff have a greater influence on outcomes than volume of cases. He also provided data on the growth of cardiac services in South Carolina.

COMMENT: Doug Bryant (18) provided a written version of the comments made at the Columbia public hearing by Phillip Wright from Mary Black Health Systems. They support the provision allowing 3 hospitals to participate in the C-PORT study, and stated that the American College of Cardiology (ACC)'s position was "...recommends PCI only in facilities with on-site open heart surgery until further data are available," which is what the C-PORT study is designed to provide. They noted that Georgia and North Carolina are among the states already participating in the study, and provided a copy of the relevant Georgia CON standards. They also submitted the Executive Summary of an article from the Society for Cardiovascular Angiography and Interventions (SCAI) that stated that there are facilities in 28 states and a number of foreign countries currently performing PCI without backup and provided a consensus statement of recommendations. Also included was a letter from Dr. Thomas Aversano, the Director of the C-PORT study.

COMMENT: Roper St. Francis (4) opposed the C-PORT study provision because there are no ACC/American Heart Association (AHA) criteria for performing elective PCI without Open Heart backup.

COMMENT: Palmetto Health (19) opposed the C-PORT study provision because performing elective PCI without open heart backup is not supported by the ACC, and they believe that the study is being used as an attempt for hospitals that provide diagnostic catheterizations to develop interventional programs.

COMMENT: Spartanburg Regional (20) expressed concern about the C-PORT study provision because they support the ACC and AHA guidelines. Access to cardiac care is not an issue in the state and that patient safety is of utmost importance.

COMMENT: Providence Hospital (13) opposed the C-PORT study because elective PCIs are rarely performed on patients suffering from an acute heart attack and that the study is inconsistent with the current ACC/AHA position. They concede that Georgia has allowed 10 hospitals to participate in the study but only one of the facilities was located within 40 miles of an existing provider. Only 2 hospitals in South Carolina have received a CON to provide emergent PCI without open heart backup. The study also does not consider the need for additional providers or the impact on existing providers.

COMMENT: Dr. Mac Leopard (14) opposed a study that is not consistent with the ACC/AHA guidelines when the majority of the people live within relatively easy access of existing therapeutic cath providers.

COMMENT: Dr. Lanneau Lide (15) opposes the C-PORT study because it uses mortality as the primary outcome measure with additional outcomes data collected for stroke, heart attack, revascularization, etc. While complications are rare they do happen and require immediate intervention. There is sufficient cardiac cath capacity statewide and the waiver would create an unnecessary duplication of services. The study has not enrolled as many patients as planned and there are questions about its funding. However, he does support the requirement of Standard 9B (II-45) that if a hospital does apply for C-PORT study participation they must simultaneously apply to offer emergent PCI as provided for in Standard 8 on pages II-43-45.

STAFF RESPONSE: The current ACC/AHA/SCAI guidelines do not endorse performing elective PCI without on-site open heart backup. However, based in part on data from the original C-PORT study, these organizations now accept that emergent PCI can be safely performed without backup under controlled conditions. These guidelines form the basis of Standard 8 on pages II-43-45 in the Draft. The purpose of the current C-PORT study is to determine if elective PCI can be done safely without on-site open heart backup. As the SCAI consensus document provided through Doug Bryant (18) indicated, there are currently hospitals in 28 states performing elective PCI without on-site open heart surgery backup and it is also performed to varying degrees in other countries.

A recent study presented at the SCAI-ACCi2 Summit that found that hospitals with and without open heart backup had similar rates of procedural success, overall complications, emergency surgery and mortality. To quote Dr. Michael Kutchner, the lead investigator of that study: "The implications of this are that off-site PCI centers can provide excellent care to patients if the program is thoughtfully developed. But we shouldn't be extrapolating from this to encourage the widespread proliferation of off-site PCI. We don't want this to be a message that every hospital should go out and develop an off-site program."

According to Dr. Aversano, the lead investigator of the C-PORT study: "I would be very enthusiastic about adding SC sites to the C-PORT project, assuming that those sites have the capability to meet the study inclusion criteria. Perhaps the most difficult is the volume criteria (they must have the capability to perform a minimum of 200 PCIs per year. This is the SUM of the primary and elective PCIs.)." Staff is aware of the concerns

expressed about South Carolina patients and facilities participating in this study. However, since the purpose of the study is to provide the data the experts need to determine whether their guidelines should be revised, staff recommends allowing South Carolina hospitals to apply to participate in the study within defined parameters.

STAFF COMMENT: Concern was raised that because the Department was limiting participation to 3 hospitals, we could approve a CON for participation in the study, only to have the applicant rejected as unsuitable by the C-PORT program. In conversations with Dr. Aversano he stated a willingness to develop a preliminary C-PORT study application for a SC hospital to complete prior to CON review. C-PORT would report that an applicant was deemed "acceptable" as a study participant should a CON be approved for that facility. Staff believes that this proposal would prevent such a situation from occurring. Because we could not approve a facility that is unacceptable to the study, the number of potential participants would not have to be restricted in the Plan. Assuming that this proposal is approved in the Plan, Dr. Aversano will provide the preliminary application to interested hospitals upon request.

COMMENT: Mary Black through Doug Bryant (18) disagreed with Standard 9A on page II-45. They believe that the 30 minutes one-way driving time is an unnecessary restriction on participation.

STAFF RESPONSE: Geographic isolation may be a justification for allowing the provision of emergent PCI without open heart backup. However, elective PCIs are scheduled events. Locating participants further from existing providers can improve patient access to this study. However, allowing participants to be closer to existing providers can provide study participants with quicker access to medical backup should it become necessary. In addition, the applicant must have an agreement with an open heart provider to accept patients as part of the study control group and such an arrangement may be more feasible if the facilities are closer together. For these reasons, staff recommends removing this travel time standard, although we suggest the Committee weigh this proposal and its impact carefully.

COMMENT: Mary Black through Doug Bryant (18) disagreed with Standard 9B on page II-45, stating it was an unnecessary burden to require a hospital to also apply to provide emergent PCI if it was not already offering this service.

STAFF RESPONSE: The Atlantic C-PORT Trial Manual of Operations v3.0 includes the following study inclusion criteria that participating sites must meet:

2. agree to complete an elective PCI development program *(and a primary PCI development program if not already completed)* **[emphasis added]** and ...
6. *perform primary PCI 24/7* **[emphasis added]**.

It also states "While local state regulations may provide alternative minimum numbers, in no case should the number of primary PCI performed fall below 36 per year, the ACC/

AHA guideline." South Carolina uses the ACC/AHA figure of 36 per year for emergent/primary PCI in Standard 8 of the Plan.

If a facility failed to comply with this standard it would not be approved by C-PORT as an acceptable study participant. Therefore, the CON application would have to be denied. Staff also does not see the consistency in wanting to provide elective PCIs to participate in a study but not being willing to offer life-saving PCIs on an emergency basis.

COMMENT: Mary Black through Doug Bryant (18) requested that Standard 9C (II-45) be reduced from 600 to 300 diagnostic caths if Standard 9B is not removed.

STAFF RESPONSE: The study guidelines from C-PORT recommend a minimum of 100 PCIs (emergent plus elective) in the first year of operation and a minimum of 200 in the second year in order to participate. To quote an email response from Dr. Aversano: "What C-PORT does not want - and I assume the State of SC does not want - is to create low volume PCI programs. 200 cases per year is already a liberal, but I think well-supported PCI volume minimum; we do not want to fall below that." In another reference, he estimates that 30% of diagnostic caths lead to a therapeutic cath. The standard of 600 diagnostic caths in Standard 9C x 30% = 180, which approximates the minimum number of PCIs the C-PORT study is looking for in the 2nd year of participation.

Staff recommends amending Standard 9C to clarify that an applicant must be able to perform 100 PCIs in the 1st year of participation and a minimum of 200 in the 2nd year to qualify to participate. Dr. Aversano indicated that there are alternative measures that the C-PORT study can use in their analysis to determine whether a facility can generate the minimum number of cases required to participate when they do their acceptability analysis. Staff recommends adding flexibility for the experts to determine whether they believe a facility can qualify for participation, but does not believe that allowing a blanket reduction of the minimum to 300 diagnostic caths per year will ensure a sufficient number of cases to allow participation in the study and does not endorse this change. Staff recommends the following new wording for Standard 9C on page II-45:

> Applicant hospitals should have a demonstrated history of operating a cardiac catheterization program at volumes adequate to meet the C-PORT standards. An applicant must **either** have performed at least 600 diagnostic cardiac catheterization procedures for the most recent year of data prior to **submitting** ~~submission~~ of the application **or otherwise have successfully demonstrated to the C-PORT program that they are** ~~and must be~~ **capable of performing a minimum of 100** ~~200~~ **PCI's** (elective plus primary) **in the first** ~~per~~ year **of participation and 200 by the second year of participation in the study**.

COMMENT: Georgetown (10 and 27) recommended that Standard 9E (II-45) be revised to allow a hospital to participate in the study for its duration rather than for only 3 years from the date of the first procedure.

STAFF RESPONSE: As originally written, this standard was comparable with that of other CON states for which staff was able to find this information. However, staff believes that it requires further clarification and recommends the following revision:

> The applicant, if approved, would be allowed to provide PCI's without open heart surgery back-up as part of the study for a maximum of three years from the time the first procedure was preformed. **The applicant would only be approved to perform elective PCIs that are done as part of the C-PORT study. At any during the ~~end of that time~~ study** period**, should the applicant lose the approval of the C-PORT study for participation, or should the C-PORT study declare the trial completed before the applicant has participated for three full years,** the authorization to perform elective PCI's would expire, although the applicant would still be authorized to perform primary PCI's as provided for in criterion B above.

COMMENT: Mary Black through Doug Bryant (18) proposed striking Standard 9 (II-45) in its entirety and replacing it with the following alternative wording:

> The Department staff may approve applications to perform Percutaneous Coronary Intervention (PCI) in hospitals without on-site cardiac surgery for the purpose of participation in medical research. Applicants approved for such research studies must be participants in the Atlantic Cardiovascular-Patient Outcomes Research Team study (C-PORT) and shall meet all of *the* [sic] standards outlined in the most current C-PORT operations manual/protocol. If a hospital fails to receive approval from the Department for this service or if the hospital is expelled or otherwise loses the approval to participate the Department's approval will be simultaneously withdrawn without the hospital having the right to an appeal.
>
> Research studies approved by the Department for this purpose shall be determined by utilizing the most current data available and not limited to the data listed in the 2008-2009 State Health Plan. Performance of PCI at participating sites is permissible only for the duration of the study and only for patients who consent to participate. Under no circumstances shall the project be approved for more than three (3) years from the date of the first procedure. A maximum of three (3) hospitals statewide may be approved to participate in the research study.
>
> Approval of such research shall not be construed to be permission or approval for any other activity than the participation in a specific medical research study.
>
> **STAFF RESPONSE:** Staff notes that the C-PORT Director is willing to perform a preliminary analysis as to whether a particular hospital is capable of qualifying to participate in the study prior to a CON being issued. Staff has already recommended accepting that offer and incorporating it as a requirement to be complied with before a CON could be approved. The Mary Black proposal removes all the review standards the Department would use to evaluate a CON

application and staff does not recommend accepting this entire recommendation. However, staff does recommend incorporating the sentiment of the final statement as a new Standard F in this section:

> Approval of a CON for participation in the C-PORT study shall not be construed to be permission or approval for any other activity than the participation in this specific medical research study.

PROPOSED NEW C-PORT STANDARD (PAGE II-49)

(9) Hospitals in South Carolina may be approved to perform elective Percutaneous Coronary Intervention (PCI) without on-site cardiac surgery for the purpose of participation in the Atlantic Cardiovascular-Patient Outcomes Research Team study (C-PORT). Participation in the C-PORT study requires CON approval and applicants must follow the process stated below:

A. Prior to the submission of a CON application, a hospital must first submit a preliminary application to the C-PORT Study Director and be deemed "acceptable" as a study participant before a CON application can be approved for this service. The C-PORT Study Director will establish this preliminary application process based upon the program requirements stated in the current Manual of Operations. A hospital that fails to receive an "acceptable" preliminary C-PORT rating cannot be approved for a CON. However, receipt of an "acceptable" preliminary rating does not guarantee that a CON will be approved for participation in the study.

B. If they are not already approved to do so, applicants must simultaneously apply for and obtain a CON to provide primary percutaneous coronary intervention (PCI) services as required as a condition for participation in the C-PORT study.

C. Applicant hospitals should have a demonstrated history of operating a cardiac catheterization program at volumes adequate to meet the C-PORT standards. An applicant must either have performed at least 600 diagnostic cardiac catheterization procedures for the most recent year of data prior to submitting the application or otherwise have successfully demonstrated to the C-PORT program that they are capable of performing a minimum of 100 PCI's (elective plus primary) in the first year of participation and 200 by the second year of participation in the study.

D. Because a random 25% of the patients presenting to the applicant must be transferred to a facility with comprehensive cardiac catheterization laboratories as a research protocol, the applicant must provide a transfer agreement with a provider indicating their willingness to participate in the study.

E. The applicant, if approved, would be allowed to provide PCI's without open heart surgery back-up as part of the study for a maximum of three years from the time the first procedure was performed. The applicant would only be approved to perform elective PCIs that are done as part of the C-PORT study. At any time during the study period, should the applicant lose the approval of the C-PORT study for participation, or should the C-PORT study declare the trial completed before the applicant has participated for three full years, the authorization to perform elective

PCI's would expire, although the applicant would still be authorized to perform primary PCI's as provided for in criterion B above.

F. Approval of a CON for participation in the C-PORT study shall not be construed to be permission or approval for any other activity than the participation in this specific medical research study.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

OPEN HEART SURGERY STANDARDS (II-52-58)

COMMENT: Spartanburg Regional (20) revised their 2006 open heart utilization data.

STAFF RESPONSE: Staff has changed the number on page II-58 to 401 surgeries.

COMMENT: Spartanburg Regional (20) stated that of the 17 open heart surgery providers in the state, only 35% of the programs met the minimum volume of 200 surgeries per OR and only 7% performed 350 surgeries in 2006.

STAFF RESPONSE: We do not have utilization data from the VA Hospital in Charleston. Only 6 of the 16 programs in South Carolina for which we have data performed more than 200 surgeries per OR in 2006 (37.5%). The statewide average is approximately 156 surgeries per OR. Staff believes the "7% performed 350 surgeries in 2006" is a typo and should be "7 **programs** performed 350 surgeries in 2006." However, the point is made that there is additional open heart surgery capacity available statewide.

COMMENT: Dr. Mac Leopard (14), on behalf of Providence, noted the decreasing open heart surgery volume statewide due primarily to increased emergent PCI. He also discussed the excess capacity in existing providers and stated his opposition to any amendments that would provide special exceptions to the Standards.

COMMENT: Providence Hospital (13) and Palmetto Health (19) support the proposed Open Heart Surgery Standards on pages II-52-55, including the revision of Standard 5B2 (II-53) to a ratio of 7 diagnostic caths to 1 open heart surgery based on more current data. Spartanburg Regional (20) also supported using the 7:1 ratio. Providence also opposes modifying any standard to benefit a particular facility. They also noted the excess capacity statewide and submitted documents relating to the proposed Open Heart Standards in the Draft 2006-2007 Plan and the Administrative Law Judge ruling on the Lexington Medical Center Open Heart Surgery CON appeal.

COMMENT: Georgetown (27) opposed Standard 5B2 on page II-53 being revised to a ratio of 7 diagnostic caths to 1 open heart surgery and recommended that the standard be deleted. They are not aware of any other states that use such a ratio as a CON requirement, or any clinical studies suggesting this ratio is appropriate, and consider the ratio susceptible to fluctuation. They also dispute the perception that a diagnostic cardiac cath is a prerequisite for open heart surgery, because cardiac CT is being increasingly relied upon instead.

STAFF RESPONSE: This standard was first incorporated in the 1995 Plan as a ratio of 4:1 diagnostic caths to open heart surgeries and remained unchanged until the current update based on more current data. Staff compared the South Carolina 3-year ratio of 6.96:1 with available data from North Carolina and Georgia. Both states had comparable but higher average ratios (North Carolina's was 7.48:1 and Georgia's was 8.04:1). Staff

recommends retaining the 7:1 ratio for this Plan, and then have the Committee evaluate whether to keep this standard or create an alternative standard in next Plan.

COMMENT: Lexington Medical Center (16) requested that the Standards 5 and 6 that appeared in the Draft 2006-2007 Plan be re-introduced into the current Plan. The differences between these versions are as follows:

(5) New open heart surgery services shall be approved only if the following conditions are met:

B. An applicant must project that the proposed service will perform a minimum of 200 adult open heart surgery procedures annually per open heart surgery **program**, ~~unit for adult services (70 percent of functional capacity).~~ within three years after initiation (the standard for pediatric open heart surgery shall be 100 procedures annually per open heart surgery program within three years after initiation):

1. using a standard of every **four (4)** ~~seven (7)~~ diagnostic cardiac catheterizations performed generating one (1) open heart surgery; the applicant must demonstrate that the facility performs sufficient diagnostic cardiac catheterizations to generate the minimum volume of open heart surgeries.

C. No new open heart surgery programs shall be approved if the new program will cause the annual caseload of other programs within the proposed service area to drop below 350 adult procedures or 130 pediatric procedures per open heart surgery **program** ~~unit~~.

(6) Notwithstanding the foregoing and notwithstanding any other standard contained in this Plan, an applicant shall be deemed to have demonstrated that need exists and that improved accessibility outweighs the adverse effects of duplication if the applicant demonstrates compliance with the following four criteria:

A. There are no other open heart surgery programs located in the same county as the applicant; and

B. The proposed facility currently offers cardiac catheterization services and provided a minimum of 1,200 diagnostic catheterizations equivalents, without regard to patient origin, in the previous year of operation; and

C. The applicant currently has more than 300 licensed general acute care hospital beds; and

D. The applicant had more than 65,000 emergency room visits in the previous year of operation.

STAFF RESPONSE: These proposed standards went out for public comment as part of the 2006-2007 Draft Plan development process. Comments in favor of these standards were received from representatives of Lexington Medical Center. Comments received in opposition to these proposed standards or in support of the prior standards were received from SCHA, Greenville Hospital System, Roper, Providence, Georgetown Hospital System and Palmetto Health. Based on the preponderance of support being for the previous standards, staff recommended the incorporation of the previous standards in the 2008-2009 Draft Plan. At the December 2007 Committee meeting the Committee was given the option to re-insert the standards proposed by Lexington Medical Center into the Draft Plan, but the Committee opted not to do so. Staff does not recommend incorporating these changes.

COMMENT: Richard Baer (17) recommended that the measurement of open heart capacity (Standard 3, page II-53) be changed from "unit" to "program" for the following reasons. First, open heart ORs are commonly also used for vascular, thoracic, and other procedures, so just counting open heart surgeries under-reports the total utilization of the ORs. Second, there are no studies measuring quality based on volume per OR, just per program. Finally, most Southeastern states with CON programs regulate Open Heart based on the number of programs, not units.

STAFF RESPONSE: Staff does not recommend accepting this recommendation. While other procedures can be done in an open heart suite, the Department must determine whether there is need for additional capacity to serve patients requiring open heart surgery. To measure "capacity" we take the number of existing open heart suites, apply the number of surgeries that can be performed annually to each suite, and assign this total as the overall annual capacity of the facility. A hospital with 3 or 4 open heart units does not have a capacity of 200 procedures per year. The minimum volume of 200 procedures to run a quality program (Standards 4 and 5B on page II-53; Staff Finding 5 on page II-57) is not the same measurement as the number of surgeries a facility is capable of performing with the available equipment. Where capacity is used as a standard for other services in the Plan it is calculated based on the total number of units available; it would be inconsistent to use "program" as the measure of capacity for this individual service. North Carolina uses a similar methodology to ours. Their capacity is stated as 400 surgeries per year per bypass machine but they require a facility to be at 80% of capacity before additional machines could be approved (i.e. 320 surgeries per year versus our 350). Their overall utilization was 39.0% of capacity in 2006 and they currently project no need for additional machines. Staff believes this Standard should not be amended.

COMMENT: Richard Baer (17) recommended that Standard 5A on page II-53 be amended from "...an annual minimum of 350 open heart surgery procedures per open heart surgery unit..." to "...an annual minimum of **200** open heart surgery procedures per open heart surgery **program...**" Also, Standard 6 on page II-54 should be amended from "...cause the annual caseload of other programs within the proposed service area to drop

below 350 adult procedures...per open heart surgery unit" to "...cause the annual caseload of other programs within the proposed service area to drop below **200** adult procedures...per open heart surgery **program.**" He noted that a number of South Carolina providers are performing fewer than 350 surgeries annually with quality outcomes.

STAFF RESPONSE: The issue of using "program" rather than "per unit" was responded to above. While it is true that a number of the existing providers are performing less than 350 surgeries annually, this does not indicate that there is a need for the establishment of additional open heart surgery programs in the state. Staff does not recommend accepting these changes.

COMMENT: Richard Baer (17) recommended that the statement that "The benefits of improved accessibility will not outweigh the adverse effects of duplication in evaluating Certificate of Need applications for this service" (page II-57) should be eliminated. He contended that improved access should be the most important criterion for this service. He also stated that recent research indicated that volume alone is not a good predictor of outcomes, because physician proficiency and the quality of staff also impact the results. The proposed standards also limit the ability of new providers to be approved.

STAFF RESPONSE: Section 106 1.d. of Regulation 61-15 requires the Department to make a general statement as whether the benefits of improved accessibility may outweigh the adverse effects of duplication for every service in the Plan. Therefore, staff cannot accept the recommendation to eliminate this general finding. Staff does concur that there is not an absolute relationship between volume and quality of outcomes. The ACC/AHA Pocket Guideline to Coronary Artery Bypass Graft Surgery states: "It is also true that there is a wide variation in risk-adjusted mortality rates in low-volume situations. Thus, some institutions and practitioners maintain excellent outcomes despite relatively low volumes." However, this does not mean that this required general statement should be amended.

COMMENT: Spartanburg Regional (20) noted that Finding 5 in the 2004-2005 Plan included the following statement: "Therefore, the Department staff is directed to evaluate low-volume open heart surgery providers and recommend to the State Health Planning Committee any changes deemed necessary by staff."

STAFF RESPONSE: Staff determined that we do not have the authority to shut down a program once it is operational, even if it is not meeting the minimum utilization standards for the service. This authority to revoke would require legislative action. As was noted in Chapter I, a number of organizations are compiling information on quality indicators for different services. As these databases are still under development, staff suggests that a table comparing appropriate quality data and benchmarks for open heart providers could be incorporated into the next Plan.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

MEGAVOLTAGE RADIOTHERAPY & RADIOSURGERY (II-59-68)

NOTE: BECAUSE OF THE NUMEROUS CHANGES TO THIS SECTION, A PROPOSED REVISED VERSION OF THIS SECTION IS ATTACHED

COMMENT: Spartanburg Regional (20) supports the differentiation between standard radiation therapy services and specialized radiation therapy services.

COMMENT: Because of the differing planning capacities, SCHA (12) recommended that the Radiotherapy section be segmented to reflect the need for standard services and the need for more specialized techniques and modalities such as total body irradiation.

COMMENT: Georgetown (10) recommended that the radiotherapy section be segmented to reflect the standard services and the more specialized techniques and modalities.

COMMENT: Grand Strand Regional (30), Summerville Medical Center (31), Trident Health System (32), and Colleton Medical Center (33) disagreed with a statement in the section defining linear accelerator capacity on page II-60. It states: "At this time, the [*emphasis added*] linear accelerators at MUSC and the Cyberknife at Roper Hospital (CON 8-10-06) are determined to meet this definition..." Of the 4 linear accelerators at MUSC, only 1 was designated specifically in a CON (SC-05-45) to provide the pediatric and other time-intensive treatments referenced in this section. It is their contention that the other 3 linear accelerators should be treated as standard linear accelerators and the facility and regional capacity calculations should be adjusted. They also recommended that the Plan specifically identify each linear accelerator considered to have a 4,000 treatment per year capacity and the basis for this designation.

STAFF RESPONSE: Grand Strand *et. al.* are correct that this CON allowed MUSC to replace their 3rd linear accelerator with a newer piece of equipment and reserve the replaced piece for special cases pertaining to the pediatric patient population and time-intensive treatments. As part of the re-write of this section of the Plan, staff is clarifying which linear accelerators are considered to have a capacity of 4,000 treatments per year.

COMMENT: To clarify that all radiotherapy services in a given service area have the potential to affect one another, Georgetown (10 and 27)) requested that the following wording be added to the Radiotherapy section on page II-60: "Specialized radiotherapy techniques and modalities such as total body irradiation, IMRT, and Cyberknifes may have an adverse impact on the utilization of existing standard linear accelerators."

STAFF RESPONSE: Staff notes that the addition of any new service or technology has an impact on the referral and utilization patterns in the service area. Staff is not opposed to incorporating a statement noting the interrelationship between the different treatment modalities.

COMMENT: Roper St. Francis (4) stated that the utilization chart on II-61 would be more useful if the treatments per accelerator were changed to a total number of treatments and a column added that lists the total number of patients treated.

STAFF RESPONSE: The chart is question shows the utilization of each provider per linear accelerator (# treatments / # accelerators). The data referenced by Roper St. Francis already appear on pages II-66-67, so it would be duplicative to present the same information twice. Staff does not recommend this change. Staff is not opposed to the recommendation that the total number of patients treated be listed. However, this piece of data is not reported on the Joint Annual Report (JAR), so it would require a special survey for staff to obtain this information.

COMMENT: Georgetown (27) commented that "is providing" in the 2nd sentence of Standard 2 on page II-62 could be construed as only applying to providers already providing specialized radiotherapy services and provided the following revision:

> A facility must document that it is providing **or will provide** these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.

STAFF RESPONSE: Staff recommends incorporating this recommendation in the revised version of this section of the Plan.

COMMENT: Accuray (3), Roper St. Francis (4), Georgetown (10), SCHA (12), Spartanburg Regional (20), Carolinas HealthCare System (21) stated that Standard 2 on page II-62 of 4,000 treatments/year is too high for a Cyberknife and should be reduced. They recommended a standard of 900 treatments per year.

COMMENT: In a different section of their comments, Accuray (3), the manufacturer of the Cyberknife, stated that a typical LINAC based radiosurgery system would provide 4 treatments per day, 5 days per week, 50 days per year for a maximum capacity standard of 1,000 treatments per year per unit.

COMMENT: Carolinas HealthCare System (21) also proposed an alternative measurement of capacity based the number of patients treated annually; other states have CON standards that vary from 250 to 325 patients annually.

COMMENT: Spartanburg Regional (20) recommended the following volume requirements for a Cyberknife, with the unit operating at 80% of capacity by Year 3:

Year 1: 250 treatments
Year 2: 500 treatments
Year 3: 750 treatments

STAFF RESPONSE: Staff agrees that the 4,000 capacity standard was set too high for the Cyberknife at Roper. The measurement of capacity for Cyberknifes has been amended to 1,000 treatments annually, based on the methodology proposed by Accuray (3). Staff does not recommend accepting the Spartanburg Regional proposal. The standard elsewhere in the Plan is for a facility or service to be at 50% of capacity by the end of the 3rd full year of operation. As noted, we do not currently collect data on the number of patients treated annually, so it would require an additional data collection effort to incorporate the Carolinas proposal. Staff also sees the potential range of 75 patients in this proposal as providing too much leeway, and does not recommend it.

COMMENT: Georgetown (10) commented that Standard 4B on page II-62 should be amended as follows:

> an applicant, **whether the expansion occurs at the existing site or at an alternate location in the service area,** must project that the proposed service will perform a minimum number of treatments equal to 50 percent of capacity annually within three years of initiation of services, without reducing the utilization of the existing machines in the service area below the 80 percent threshold. **The applicant must document where the potential patients for this new service will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. Letters of support from referring physicians, with expected annual referral volumes, must be included.**

COMMENT: SCHA (12) made a similar proposal without the addition in the first sentence regarding existing sites or alternate locations.

STAFF RESPONSE: Georgetown's initial comment referring to the expansion of services is out-of-place. Standard 4B is for the establishment of new radiotherapy services. This comment is more applicable for Standard 5 that relates to the expansion of existing services. Their second comment regarding documenting where the potential patients will come from should be incorporated into Standard 4B. Letters of support from physicians are already addressed in Standard 6 and their final comment should be addressed there.

COMMENT: Georgetown (27) commented that the Plan should clarify that an "existing service" may provide services at more than one location by making the following revision to Standard 5 on page II-62:

> Expansion of an existing service, **whether the expansion occurs at the existing site or at an alternate location in the service area,** shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for the past two years and can project a minimum use rate of 50 percent of capacity per year on the additional equipment within three years of its implementation.

COMMENT: SCHA (12) proposed the following addition to Standard 5 on page II-62:

> Expansion of an existing service shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for the past two years and can project a minimum use rate of 50 percent of capacity per year on the additional equipment within three years of its implementation. **If the additional equipment is a specialized radiotherapy unit as described in Standard 2, then the existing provider may propose an annual capacity for that additional equipment, based on the specialized use of the equipment by that applicant. If this proposed annual capacity can be justified by the applicant, then this capacity will be used in CON application calculations, as well as future capacity calculations, for that applicant.**

COMMENT: Spartanburg Regional (20) recommended that a standard be created that requires an applicant for a new service to document where the potential patients will come from and where they are currently being served.

COMMENT: Spartanburg Regional (20) recommended that Standard 6 (II-62) be revised to require that the physician letters of support should come from physicians who typically refer patients to these services.

COMMENT: Georgetown (10) had the previous comment on Standard 4B that is more appropriately addressed in Standard 6 on page II-62:

> Letters of support from referring physicians, with expected annual referral volumes, must be included.

STAFF RESPONSE: Staff has incorporated the comments on Standards 4B - 6 into the revised version of this section of the Plan. Please refer to the attached document for the proposed changes.

COMMENT: Accuray (3) proposed that Linac based radiosurgery programs be allowed to develop within geographic areas or population zones. The needs criteria would be similar to a standard radiation therapy unit, but instead of 7,000 treatments per year as capacity, 900 treatments should be used.

COMMENT: Roper St. Francis (4) requested that the categorization of their Cyberknife be changed to radiosurgery and the capacity be reduced.

STAFF RESPONSE: Staff recommends amending the capacity of the equipment to 1,000 treatments per year.

COMMENT: Roper St. Francis (4) questioned why the capacity for Radiosurgery equipment (Standard 1 on page II-64) was decreased from the previous Plan and opposed the change.

COMMENT: Palmetto Health (19) requested that the capacity be re-raised to 500 treatments per year, because improvements in the new Gamma Knife system reduces "in-treatment-room time" so that 3-4 procedures per day can be performed.

STAFF RESPONSE: "Gamma Knife" standards were first incorporated in the 1997 Plan. Using the most current information available at that time, the capacity was established as 500 cases per year. Recent survey data show that 91% of these units in the U.S. had program volumes of less than 300 patients, while only 2% had volumes above 400 patients. The average was 177 cases per site, while the only site in the state averages slightly over 200/year. An average utilization of less than 100 cases per year is required for financial feasibility. Staff also notes that the Gamma Knife utilization at Palmetto Health actually decreased from 2006 to 2007. Based on these numbers, the capacity in the Draft Plan was revised to 300 cases per year and staff believes this capacity standard to be appropriate.

COMMENT: Presbyterian Healthcare (23) recommended to add the word "dedicated" to Standard 1 on page II-64 to clarify it is a full-time piece of equipment.

STAFF RESPONSE: Staff has no objection to this proposal.

COMMENT: MUSC (28) commented that using the entire state as a service area for Gamma Knife services fails to ensure geographic accessibility to services. Other regional services base their standards on either multiple county service area or travel times (i.e. 60 or 90 minutes). They recommended the following new Standard 2 on page II-64 and the renumbering of subsequent standards:

> Gamma Knife services should be available within 90 minutes for the defined service area population.

STAFF RESPONSE: Staff proposes the following alternative wording:

> The service area for a dedicated Stereotactic Radiosurgery unit is defined as all facilities within 90 minutes one-way automobile travel time.

COMMENT: MUSC (28) commented that the historical utilization of a sole provider of Gramma Knife services is not an accurate measure for projecting future utilization of an additional provider. The slow adoption of the service understates the number of potential patients that could benefit from the service. They propose that the current Standards 2A and 2B on page II-64 be amended as follows:

(2) New Radiosurgery services shall only be approved if the following conditions are met:

A. all existing units have performed at a combined use rate of **70** ~~80~~ percent of capacity for the most recent year; and

B. an applicant must project that the proposed service will perform a minimum of 200 procedures annually within three years of initiation of services, without reducing the utilization of existing units below the **70** ~~80~~ percent threshold. **In cases where existing providers are performing below 70 percent of optimal utilization for the most recent two years, the applicant must document that it will not cause the existing service to fall more than 10 percent below its most recent utilization levels**;

STAFF RESPONSE: Staff is already proposing to reduce the capacity of a Gamma Knife from 500 to 300 treatments per year. As stated earlier, the national average was 177 treatments per machine and approximately 100 treatments per year are required for financial feasibility. Amending the standard from 80% to 70% of capacity would reduce the number of treatments required before a new provider could be approved in an service area from 240 to 210 per year. The only existing Gamma Knife in the state has had relatively stable utilization for the past 4 years (225, 214, 240, and 232 treatments/year) but just barely at or below the 240 number required as currently written. Staff will defer to the Committee as to whether the capacity requirements should be further reduced. Staff notes that these proposals for 2A and 2B conflict. Standard 2A requires that the existing providers have to be at 70% capacity for the most recent year of utilization before a new service could be approved. Standard 2B then says that if the existing providers are below 70% of capacity, then a new provider can be approved, as long as it doesn't have more than a 10% impact on the existing providers. Standard 2B gives an applicant 3 years to get up to 200 treatments/year without bringing the existing providers below 70%. If an approved provider is under 70% for its first 2 years of operation, does this allow a new applicant to be approved as long as it doesn't impact the current provider by more than 10%? The addition of a new provider before the 3rd full year of operation could impact the existing provider(s) attempts to get to the minimum threshold by the deadline. Staff also questions whether a decrease of 10% would be meaningful as a standard. If a facility did 130 procedures in the last year of data, a new applicant would only have to prove that they wouldn't take away more than 13 cases from the current provider in order to be approved. Staff cannot recommend the proposed 2B provision allowing an additional provider even if the existing providers are below capacity.

COMMENT: Spartanburg Regional (20) recommended that a standard be created that requires an applicant for a new service to document where the potential patients will come from and where they are currently being served.

STAFF RESPONSE: This is already addressed in Standard 4 on page II-64. No additional standard is recommended.

COMMENT: Presbyterian Healthcare (23) noted that Standard 7A on page II-65 refers to the operation of the facility being overseen by both board certified neurosurgeon and a board certified radiation oncologist. They are requesting clarification of this standard, as to who is really in charge? As written it appears to require 2 people to be in charge.

STAFF RESPONSE: Staff has re-worded this section:

the ~~operation of the~~ radiosurgery unit will **have** ~~be overseen by~~ a board certified neurosurgeon and a board certified radiation oncologist, both of whom are trained in stereotactic radiosurgery;

COMMENT: MUSC (28) stated that the Medical University Hospital Authority (MUHA) serves as the academic training facility for 49 medical residency programs. Neurosurgery, Otolaryngology, and Radiation Oncology residents benefit from on-site access to stereotactic training. MUHA is also initiating a Radiation Physics residency program. In addition, the Accreditation Council for Graduate Medical Education (ACGME) and other accreditation bodies are requiring residency training sites to include stereotactic surgery experience to residents. Because access to state-of-the-art equipment is essential for these residency programs, MUSC is requesting the addition of the following new standard:

> Because of the unique nature and limited need for the equipment, it is preferable that Gamma Knifes be located in or operated in conjunction with teaching hospitals that offer a complete range of oncology and neurosurgery services. A "teaching hospital" means a hospital which operates multiple (more than one) medical residency training programs for programs of graduate medical education accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) and maintains a written affiliation agreement with an accredited medical school located in South Carolina, or is owned and operated by an accredited medical school in South Carolina.

COMMENT: Trident Health System (29) objected to this standard proposed by MUSC. It is their contention that definition would unnecessarily restrict the preference to a small number of facilities in the state. They further note that existing Gamma Knife programs have been successful regardless of whether they are public or private or non-profit or for-profit. There are no published studies to support the preference that Gamma Knife surgery be performed in a "teaching hospital" or in an academic environment.

STAFF RESPONSE: Staff concurs that it would be desirable for neurosurgery and oncology residents to have access to the technology and experience needed for successful completion of their training programs. However, staff has concerns with stating a "preference" for a particular hospital in a potentially competitive review process. Staff recommends that any applicant be required to state how they would facilitate access to this technology by graduate medical education programs:

> Because of the unique nature and limited need for this type of equipment, the applicant should document how they intend to provide accessibility for graduate medical education students in such fields as neurosurgery and oncology.

(G) Megavoltage Radiotherapy & Radiosurgery

Cancer is a group of many related diseases, all involving out-of-control growth and spread of abnormal cells. These cells accumulate and form tumors that invade and destroy normal tissue. Cancer is the second leading cause of death, both nationally and South Carolina, accounting for approximately 22% of all deaths. It is estimated that there were 21,860 new cases of cancer diagnosed in South Carolina in 2005 and 9,080 cancer deaths. Different types of cancer vary in their rates of growth, patterns of spread and responses to different types of treatment. The overall 5-year survival rate is approximately 62%.

Megavoltage radiation has been utilized for decades as a standard modality for cancer treatment. It is best known as Radiation Therapy, but is also called Radiotherapy, X-Ray Therapy, or Irradiation. It kills cancer cells and shrink tumors by damaging their genetic material, making it impossible for these cells to continue to grow and divide. Approximately 50% of all cancer patients receive radiation therapy at some time during their illness, either alone or in combination with surgery or chemotherapy. It can be used as a therapeutic treatment (to attempt to cure the disease), a prophylactic treatment (to prevent cancer cells from growing in the area receiving the radiation) or as a pallative treatment (to reduce suffering and improve quality of life when a cure is not possible).

Beams of ionizing radiation are aimed to meet at a specific point and delivery radiation to that precise location. The amount of radiation used is measured in "gray" (Gy), and varies depending on the type and stage of cancer being treated. Radiation damages both cancer cells and normal cells, so the goal is to damage as many cancer cells as possible, while limiting harm to nearby healthy tissue. A typical course of treatment lasts for 2 to 10 weeks, depending on the type of cancer and the treatment goal. The relevant CPT Procedure codes are: 77371-77373, 77401-77404, 77406-77409, 77411-77414, 77416, 77418, 77432 and 77470.

There are varying types of radiation treatment and definitions are often used interchangeably. The following definitions apply:

Adaptive Radiation Therapy (ART): Patient setup and/or radiation delivery is evaluated and modified periodically during the treatment course based on imaging and dose measurements made prior to or during treatment.

Conformal Radiation Therapy (CRT): Since the target often has a complex shape, CT, MRI, or PET is used to create a 3-D image of the tumor. Using the image, the computer designs the radiation beams to be shaped exactly (conform) to the contour of the treatment area. Synonyms include Conformal External Beam Radiation Therapy (CEBRT), 3-D radiation therapy (3-DRT), 3-D Conformal Beam Radiation Therapy (3-DCBRT), 3-D Conformal Radiation Therapy (3-DCRT), and 3-D External Beam Radiation Therapy (3-DEBRT, 3-DXBRT).

Conventional External Beam Radiotherapy (2DXRT) is delivered via 2-D beams using a linear accelerator. Conventional refers to the way the treatment is planned on a simulator to target the tumor. It consists of a single beam of radiation delivered to the patient from several directions. It is reliable, but is being surpassed by Conformal and other more advanced modalities because of the reduced irradiation of healthy tissue.

Because of the increased complexity of treatment planning and delivery techniques, **Electronic Portal Imaging Devices (EPIDs)** have been developed. The most common EPIDs are video-based systems; on-line digital port images are captured and analyzed before or during treatment. These systems are used for pre-treatment verification of IMRT fields and to reduce errors in patient positioning.

Fractionation: A small fraction of the entire prescribed dose of radiation is given in each treatment or session. Individual treatment plans are created to minimize the side effects for normal tissue. The typical fractionation schedule for adults is once per day, five days a week. **Hyperfractionation** (Superfractionation) is when the radiation is given in smaller doses twice a day. In **Hypofractionation**, individual doses are given less often than daily, such as 2-5 sessions.

Image-Guided Radiation Therapy (IGRT) combines IMRT with On-Board Imaging (OBI) scans. It visualizes the patient's anatomy during treatments and allows for real-time adjustment of the beams. Since tumors move between treatments and due to breathing during treatments, IGRT ensures correct patient positioning and reducing healthy tissue damage.

IMRT (Intensity Modulated Radiation Therapy) creates a 3-D radiation dose map to treat the tumor. It uses a multi-leaf collimator to modulate or control the outlines and intensity of the radiation field during cancer treatment. Because of its precision it can spare more healthy tissue, but it also requires detailed data collection and takes longer than conventional therapy.

Stereotactic Radiosurgery (SRS) is a single-session procedure, used to treat brain tumors and other brain disorders that cannot be treated by regular surgery. The patient's head is placed in a special frame, which is attached to the patient' skull. The frame is used to aim high-dose radiation beams directly at the tumor inside the patient's head. The radiation dose given in one session is usually less than the total dose that would be given with radiation therapy. However, the tumor receives a very high one-time dose of radiation with radiosurgery versus smaller fractions over time with radiation therapy. It is also known as Stereotaxic Radiosurgery or Radiation Surgery.

Stereotactic Radiation Therapy (SRT) is a similar approach as Stereotactic Radiosurgery to delivering radiation to the target tissue. However, the total dose of radiation is divided into several smaller doses given over several days, rather than a single large dose. The treatment time per session typically ranges from 30 to 90 minutes for 2-5 sessions. It can be used to treat both brain and extracranial tumors.

There are 3 types of radiation equipment available:

1. Particle Beam (Proton)

Particle beams use heavy charged subatomic particles to deliver radiation to the tumor. Unlike the other equipment forms, some particle beams can only penetrate a short distance into tissue. Therefore, they are often used to treat cancers located on the surface of or just below the skin. There are only a few facilities that operate particle beam (or cyclotron) units, which can be used to treat brain cancers and fractionated to treat other cancers. There are currently only 5 facilities in the United States and the cost of greater than $100 million will limit their expansion.

2. Linear Accelerator (X-Ray)

The linear accelerator produces high energy x-rays that are collected to form a beam that matches the size and shape of the patient's tumor. The patient lies on a movable couch and radiation is transmitted through the gantry, which rotates around the patient. Radiation can be delivered to the tumor from any angle by rotating the gantry, moving the couch, or moving the accelerator with a robotic arm. The accelerator must be located in a room with lead and concrete walls to keep the rays from escaping. A conventional linac requires modifications, such as additional equipment, in order to be used for IMRT or other advanced techniques.

Minimal equipment requirements for a linear accelerator include:

a. at least 1 teletherapy unit, with an energy exceeding 1 megavolt (MV); the distance from the source to the isocenter must be at least 80 cm;

b. access to an electron beam source or a low energy X-ray unit;

c. adequate equipment to calibrate and measure dosimetric characteristics of all treatment units in the department;

d. capability to provide appropriate dose distribution information for external beam treatment and brachytherapy;

e. equipment for accurate simulation of the treatment units in the department (in general, one simulator can service 2-3 megavoltage treatment units);

f. field-shaping capability; and

g. access to CT scanning capability.

The capacity standards for a linear accelerator vary by the capability of the equipment. A conventional linear accelerator, either with or without EPID, has a capacity of 7,000 treatments per year, based upon an average of 28 patients treated per day, 5 days per

week, 50 weeks per year. IMRT and IGRT systems (such as Tomotherapy and Novalis TX) take longer to set up and perform treatments than those relying on previously generated images. In addition, the average treatment time for highly specialized techniques such as total body irradiation or for treating children is longer. Therefore, these systems cannot treat as many patients per day and a lower capacity of 4,000 treatments per year (16 patients treated per day, 5 days per week, 50 weeks per year) is established for such equipment. At this time, 2 of the linear accelerators at MUSC, and the Tomotherapy units at Spartanburg Regional and Carolina Regional Radiation Center are determined to meet this definition and their capacities and the need calculations for their service areas have been adjusted accordingly.

There is also linac equipment designed strictly to provide Stereotactic Radiotherapy in 1-5 treatment sessions. These specialized linacs have an even lower capacity because of the treatment time associated with this type of care. The capacity for such equipment is established as 1,000 treatments per year per unit, based on 4 treatments per day, 5 days per week, for 50 days per year. The Cyberknife approved at Roper Hospital (CON 8/10/06) is the only equipment so designated, and the capacity and need calculations for this facility and service area have also been adjusted.

3. Cobalt-60 (Photon)

This modality, best known by the trade name of Gamma Knife, is used to perform Stereotactic Radiosurgery. It is primarily used to treat brain tumors, although it can also be used for other neurological conditions like Parkinson's Disease and Epilepsy. Its use is generally reserved for cancers that are difficult or dangerous to treat with surgery. The radiation damages the genetic code of the tumor in a single treatment, preventing it from replicating and causing it to slowly shrink. Installation of a Gamma Knife system costs between $3.4 and $5 million, plus an additional $0.25 to $0.5 million every 5-10 years to replenish the cobalt-60 power source.

The Gamma Knife consists of a large shield surrounding a large helmet-shaped device with 201 separate, fixed ports that allow the radiation to enter the patient's head in small beams that converge on the designated target. A rigid frame is attached to the patient's skull to provide a solid reference for both targeting and treatment. The patient is then sent for imaging, to accurately determine the position of the target. The computer system develops a treatment plan to position the patient and the paths and doses of radiation. The patient is positioned with the head affixed to the couch, and the treatment is delivered. The patient goes home the same day.

Status of South Carolina Providers

1. Linear Accelerators

There are currently 26 facilities either operating or approved for a total of 50 linear accelerators in South Carolina. In 2006, the 45 operational linear accelerators averaged 5,248 treatments per unit. The utilization for each provider per linear accelerator was:

Provider	# Accelerators	Treatments/ Accelerator
Cancer Ctr. Carolinas Eastside	1	9,700
SC Oncology Associates	2	8,710
Carolina Regional Radiation	2	7,016
Lexington Medical Ctr.	2	6,478
Roper Hospital	2	6,184
Aiken Regional	1	6,134
AnMed Health Med. Ctr.	2	6,100
Spartanburg Regional *1*	3	5,984
Rock Hill Radiation	2	5,900
Cancer Ctr. Carolinas Oconee	1	5,799
RMC-Orangeburg/Calhoun	1	5,722
Greenville Memorial Hospital	3	5,569
Cancer Center Carolinas	1	5,455
Georgetown Memorial	1	5,416
Beaufort-Hilton Head	1	5,412
Trident Regional	2	5,397
Tuomey Regional	2	5,021
Carolinas Hospital System	1	4,953
McLeod Regional	4	4,141
MUSC *2*	4	3,779
Self Memorial	2	3,347
Palmetto Health Richland	4	2,704
Beaufort Memorial Hospital	1	2,053

1 Spartanburg Regional has a Tomotherapy linac with a 4,000 treatment capacity
2 2 of the MUSC linacs have a 4,000 treatment capacity

2. Gamma Knife

Palmetto Health Richland is currently the only hospital to operate a Gamma Knife in South Carolina. A total of 240 patients received Gamma Knife treatment in 2006.

The Certificate of Need standards for Radiotherapy and Stereotactic Radiosurgery follow.

Certificate of Need Standards for Radiotherapy

Standards

(1) The capacity of a conventional linear accelerator, either with or without EPID, is 7,000 treatments per year.

(2) Linear Accelerators providing IMRT or IGRT or performing highly specialized techniques such as total body irradiation or for treating children have a capacity of 4,000 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.

(3) Linear Accelerators designed strictly to provide Stereotactic Radiotherapy has a capacity of 1,000 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.

(4) There are 13 service areas established for Radiotherapy units as shown on the following chart.

(5) New Radiotherapy services shall only be approved if the following conditions are met:

A. all existing units in the service area have performed at a combined use rate of 80 percent of capacity for the year immediately preceding the filing of the applicant's CON application; and

B. an applicant must project that the proposed service will perform a minimum number of treatments equal to 50 percent of capacity annually within three years of initiation of services, without reducing the utilization of the existing machines in the service area below the 80 percent threshold. If the new equipment is a specialized radiotherapy unit as described in either Standard 2 or 3 above, then the applicant may propose an annual capacity based on the specialized use of the equipment by that applicant. If the applicant can justify this proposed annual capacity, then this capacity will be used in CON application calculations, as well as future capacity calculations, for that applicant. The applicant must document where the potential patients for this new service will come from and where they are currently being served, to include the expected shift in patient volume from existing providers.

(6) Expansion of an existing service, whether the expansion occurs at the existing site or at an alternate location in the service area, shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for each of the past two years and can project a minimum use rate of 50 percent of capacity per year

on the additional equipment within three years of its implementation. If the additional equipment is a specialized radiotherapy unit as described in either Standard 2 or 3 above, then the existing provider may propose an annual capacity for that additional equipment, based on the specialized use of the equipment by that applicant. If the applicant can justify this proposed annual capacity, then this capacity will be used in CON application calculations, as well as future capacity calculations, for that applicant.

(7) The applicant shall project the utilization of the service and document referral sources for patients within its service area, including letters of support from physicians and health care facilities indicating a willingness to refer patients to the proposed service, with expected annual referral volumes.

(8) The applicant must affirm the following:

A. all treatments provided will be under the control of a board certified or board eligible radiation oncologist;

B. the applicant will have access to a radiation physicist certified or eligible for certification by the American Board of Radiology or its equivalent;

C. the applicant will have access to simulation equipment capable of precisely producing the geometric relationships of the equipment to be used for treatment of the patient;

D. the applicant will have access to a custom block design and cutting system; and

E. the institution shall operate its own tumor registry or actively participate in a central tumor registry.

Relative Importance of Project Review Criteria

The following project review criteria are considered to be the most important in evaluating certificate of need applications for these services:

a. Compliance with the Need Outlined in this Plan;
b. Community Need Documentation;
c. Distribution (Accessibility);
d. Projected Revenues;
e. Projected Expenses;
f. Financial Feasibility; and
g. Cost Containment.

The benefits of improved accessibility will be equally weighed with the adverse affects of duplication in evaluating Certificate of Need applications for this service.

Certificate of Need Standards for Stereotactic Radiosurgery

Standards

(1) The capacity of a dedicated Stereotactic Radiosurgery unit is 300 procedures annually. This is based on an average of 2 procedures per day times 3 days per week times 50 weeks per year.

(2) The service area for a dedicated Stereotactic Radiosurgery unit is defined as all facilities within 90 minutes one-way automobile travel time.

(3) New Radiosurgery services shall only be approved if the following conditions are met:

A. all existing units have performed at a combined use rate of 80 percent of capacity for the most recent year; and

B. an applicant must project that the proposed service will perform a minimum of 200 procedures annually within three years of initiation of services, without reducing the utilization of existing units below the 80 percent threshold.

(4) Expansion of an existing radiosurgery service shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for each of the past two years and can project a minimum of 200 procedures per year on the additional equipment within three years of its implementation.

(5) The applicant shall project the utilization of the service, to include:

A. epidemiological evidence of the incidence and prevalence of conditions for which radiosurgery treatment is appropriate, to include the number of potential patients for these procedures;

B. the number of patients of the applicant who were referred to other radiosurgery providers in the preceding three years and the number of those patients who could have been served by the proposed service; and

C. current and projected patient origin information and referral patterns for the facility's existing radiation therapy services. The applicant shall document the number of additional patients, if any, who will be generated through changes in referral patterns, recruitment of specific physicians or other changes in circumstances; and

(6) The applicant must include letters of support from physicians and health care facilities indicating a willingness to refer patients to the proposed service.

(7) The applicant must document that protocols will be established to assure that all clinical radiosurgery procedures performed are medically necessary and that alternative treatment modalities have been considered.

(8) The applicant must affirm the following:

A. the radiosurgery unit will have a board certified neurosurgeon and a board certified radiation oncologist, both of whom are trained in stereotactic radiosurgery;

B. the applicant will have access to a radiation physicist certified or eligible for certification by the American Board of Radiology or its equivalent;

C. dosimetry and calibration equipment and a computer with the appropriate software for performing radiosurgical procedures will be available;

D. the applicant has access to a full range of diagnostic technology, including CT, MRI and angiography; and

E. the institution shall operate its own tumor registry or actively participate in a central tumor registry.

(9) Because of the unique nature and limited need for this type of equipment, the applicant should document how they intend to provide accessibility for graduate medical education students in such fields as neurosurgery and oncology.

Relative Importance of Project Review Criteria

The following project review criteria are considered to be the most important in evaluating certificate of need applications for these services:

a. Compliance with the Need Outlined in this Plan;
b. Community Need Documentation;
c. Distribution (Accessibility);
d. Projected Revenues;
e. Projected Expenses;
f. Financial Feasibility; and
g. Cost Containment.

The benefits of improved accessibility will be equally weighed with the adverse affects of duplication in evaluating Certificate of Need applications for this service.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

POSITRON EMISSION TOMOGRAHY (PET) & PET-CT (II-69-71)

COMMENT: Presbyterian Healthcare (20) recommended that the last sentence of the first paragraph on page II-69 be revised to read: "It is qualitative and very sensitive, so only **small** ~~tracer~~ amounts of isotopes are needed. The word "tracer" is another word for "radiopharmaceutical," which has a different connotation than DHEC staff intended.

STAFF RESPONSE: Staff recommends accepting this change.

COMMENT: Presbyterian Healthcare (20) noted that the operator of a PET/CT must be a nuclear medicine technologist either certified for both PET and CT or dually certified in radiography. There are also ways for radiographers to cross-train for PET certification. Otherwise two technologists must operate the scanner, one in nuclear medicine/PET and a radiographer.

STAFF RESPONSE: Staff believes this information should be incorporated into the Plan for information purposes. Staff proposes changing the 3rd and 4th paragraphs on page II-69 to the following:

> The process takes around 45 minutes to an hour to perform. A Computerized Tomography (CT) scanner produces cross-sectional images of anatomical details of the body. These images are taken separately, and then fused with the PET images for interpretation. **The process requires a nuclear medical technologist certified for both PET and CT or dually certified in radiography**.
>
> Several manufacturers have now developed combined PET/CT scanners that can acquire both image sets simultaneously, giving radiologists a more complete picture in about half the time. ~~It is expected that PET/CT imaging will replace stand-alone PET imaging for most uses~~. A PET/CT scanner costs between $2.0-2.7 dollars. Installing and operating a PET scanner typically costs around $1,600,000 in capital costs plus annual staffing and operational costs of $800,000.

COMMENT: Grand Strand Regional (30), Summerville Medical Center (31), Trident Health System (32), and Colleton Medical Center (33) stated that the final sentence in the 5th paragraph on page II-69 is misleading. It states: "The addition of a CT component to an existing PET service is not considered to be a new service that would trigger CON review, although it could still be subject to review because of equipment cost." However, this does not describe industry practice. Instead of physically "adding" a separate CT to an existing PET, manufacturers/vendors sell a PET-CT unit to replace or trade-in the existing PET. They suggest the following alternative wording:

> The addition of a CT component to an existing PET service is not considered to be a new service that would trigger CON review **and is considered to be the replacement of like equipment with similar capabilities with the meaning of**

the Department's regulations~~, although it could still be subject to review because of equipment cost.~~

STAFF RESPONSE: Staff agrees with the sentiment of this recommendation, although they believe the wording should be changed to:

> The addition of a CT component to an existing PET service is not considered to be a new service that would trigger CON review **and is interpreted by the Department to be the replacement of like equipment with similar capabilities** ~~although it could still be subject to review because of equipment cost.~~

COMMENT: Roper St. Francis (4) recommended that an additional requirement be added that would require freestanding PET services not operated by a hospital to specify the referral source of those patients and from which current provider those referrals will be redirected.

STAFF RESPONSE: Standard 1 on page II-69 already requires that "Applicants for a freestanding PET service not operated by a hospital must document referral agreements from health care providers that would justify the establishment of such services." In addition, the projection of need in Standard 3 on page II-70 includes "...proposed utilization by both patient category and number of patients to be examined, and must consider demographic patterns, patient origin, market share information, and physician/patient referrals." Staff does not recommend adding an additional standard.

COMMENT: Palmetto Health (19) recommended that a standard be incorporated that would require that any new scanner not result in a current provider's volume falling below 750 procedures per year.

STAFF RESPONSE: Only 6 of the 24 (25%) of the approved PET or PET/CT providers in South Carolina performed more than 750 procedures in 2006. This proposal is not consistent with Standard 1, which encourages the availability of PET/CT at facilities providing tertiary services and allows other hospitals and providers to document why they have a need for this service. Staff does not recommend accepting this change.

COMMENT: Palmetto Health (19) recommended that applicants be required to provide an indigent care policy that is "comparable to other health care facilities in the service area."

STAFF RESPONSE: An indigent care policy is already required by the CON regulations as part of an application.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

MAGNETIC RESONANCE IMAGING (MRI)

COMMENT: Roper (4) supported the rationale for removing the criteria for MRI from the Plan.

COMMENT: SCHA (12), Palmetto Health (19), and Spartanburg Regional (20) want the MRI section retained in the Plan with the Standards from the 2004-2005 Plan re-incorporated.

STAFF RESPONSE: As was explained at the December 2007 Planning Committee Meeting, staff eliminated the MRI section found in the 2004-2005 Plan. Essentially every hospital already has at least one MRI because they have become such a standard piece of medical equipment. However, so many MRIs have been exempted from CON because they cost less than the cost threshold of $600,000 for medical equipment that we no longer have an accurate inventory of units and utilization data that would allow meaningful CON review. We know in 2003 there were approximately 115 fixed units in operation statewide, in addition to a number of shared mobile units. If there are no standards in the Plan for an equipment or service then the project is reviewed on the general criteria if it exceeds the cost threshold. Staff does not support re-adding an MRI section to the Plan.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

AMBULATORY SURGICAL FACILITY (II-72-80)

STAFF COMMENT: Staff recommends that the 1st paragraph of the Ambulatory Surgical Facility section on page II-72 be amended as follows to bring the definition in the Plan current with the definition in DHEC Regulation 61-91, Standards for Licensing Ambulatory Surgical Facilities:

> Ambulatory surgery, often described as outpatient or same-day surgery, may be provided in either a hospital or a freestanding Ambulatory Surgical Facility (ASF). An ASF is **a distinct, freestanding, self-contained entity that is organized, administered,** equipped and operated exclusively for the purpose of performing surgical procedures **or related care, treatment, procedures, and/or services, *e.g.*, endoscopy,** for which patients are scheduled to arrive, receive surgery, **or related care, treatment, procedures, and/or services,** and be discharged on the same day. The owner or operator makes the facility available to other providers who comprise an organized professional staff, **i.e. an open medical staff**. This definition does not apply to any facility used as an office or clinic for the private practice of licensed health care **professionals** ~~providers~~.

COMMENT: Spartanburg Regional (20) recommended the following change in the third paragraph on page II-72: "... However, hospitals have expressed concern that ASFs, **which are not hospital joint ventures**, are impacting their ability to fund their services..." They note that they participate in 2 joint venture ASFs.

STAFF RESPONSE: Staff recommends accepting this change.

COMMENT: Georgetown (10), SCHA (12), and Palmetto Health (19) recommended the following addition to Standard 3 on page II-73:

> For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. **That documentation and projections of shifts must be shared with existing providers of surgical services in the county, and the applicant must provide documentation that has occurred.** For the expansion of an existing facility, the applicant must provide patient origin information on the current facility.

STAFF RESPONSE: There is no requirement in the law or regulations that makes it the applicant's responsibility to notify the existing providers and provide them with data from their application as a condition for CON review. There are notices published in the local newspaper and the State Register (including a link from the DHEC web page) that an application is pending, and the Department has a subscription newsletter available for a fee. Existing providers can also become involved as "affected persons" during the

CON review process if they are concerned about the impact of a new ASF. Therefore, staff does not recommend accepting this comment

COMMENT: Georgetown (10), SCHA (12), and Palmetto Health (19) recommended the following addition to Standard 6 on page II-73:

> The applicant must document the potential impact that the proposed new ASF or expansion will have upon the existing service providers and referral patterns. **To validate the projected impact, DHEC will survey all existing hospitals and freestanding ASFs in the county concerning existing capacity and need. The results of these surveys will be a factor in evaluating possible adverse effects of duplication of service.**

STAFF RESPONSE: Staff does not recommend accepting this comment. Instead, efforts should be directed towards developing standard measurements of capacity for both hospital OR's and ASF's and projecting the need for these facilities. We have previously surveyed ASF's and hospitals in an attempt to do so, using either the number of cases or number of surgical minutes utilized annually as potential measures. However, we were unsuccessful in reaching consensus on what the standards should be. The difficulty is the diversity between providers. An ASF that focuses on eye surgery can potentially perform more surgeries per OR than a facility focusing on orthopedics, and a hospital maintaining 24 hour surgical coverage has a greater capacity than a facility only staffed from 7 am – 3 pm. Staff recommends that the Committee address this issue in the next Plan and adopt proposed capacity standards that can be openly discussed during the public comment period.

COMMENT: Charleston Neuroscience Institute (7) and Tom Bradley (8) requested that Standard 7 on II-73 be amended to allow for specialty ASFs, particularly to allow a facility dedicated to ophthalmic surgery. They referenced Columbia Eye Center as an example.

STAFF RESPONSE: We used to issue CONs for single specialty ASFs such as orthopaedics, etc. and some facilities went through a subsequent CON to add or change specialties. However, since DHEC Licensing standards do not make any distinction about whether a facility claims to be a single or multi-specialty ASF, CONs are now only issued as general ASFs. The only exception is Endoscopy Centers, which are restricted to performing endoscopic procedures only. The Department therefore does not restrict CONs, although the operators obviously have control over what types of surgery that will be performed. However, Standard 7 allows the Department to express its position that ASFs open and equipped for all surgical specialties will better serve the community than those targeted towards a single specialty. Staff does not recommend accepting this comment.

COMMENT: Charleston Neuroscience Institute (6), Tom Bradley (8), and Sam Tolbert (22) requested that Standard 9 on II-73-74 be deleted because it discriminates against

new facilities. When a new ASF is approved it can take 3 years to get the facility approved, licensed, and then operational long enough to obtain utilization data.

STAFF RESPONSE: Staff recognizes the time lag involved in the process, but does not recommend accepting this comment. This standard was incorporated in previous Plans to address concerns about the potential over-proliferation of ASFs. It requires that all existing ASFs in a county to have been licensed and operational for a year and for the Department to collect utilization data from all facilities before a new ASF could be approved. These data allow the CON staff to determine whether there is a need for an additional facility and what it's potential impact on existing facilities may be. We have approved approximately 15 ASFs statewide in the past 4 years.

COMMENT: Charleston Neuroscience Institute (6), Tom Bradley (8), and Sam Tolbert (22) requested that Standard 10 on II-74 be deleted because it discriminates against new facilities by not allowing more than one new ASF to be approved in a county at a single time.

STAFF RESPONSE: Staff does not recommend accepting this comment. The potential addition of a new ASF requires an evaluation of the current service area utilization and the potential impact of a new provider. Staff acknowledges that there can be more than one location in a county that could potentially support a new ASF. However, the county in which the facility is to be located was established as the service area for review purposes (Standard 1 on II-72) because we previously had applicants designating their own service areas that sometimes spread across multiple counties and in other cases only claimed part of a single county. By designating the county as the service area, we standardized the designation statewide. The standard does allow an existing provider to apply to expand based upon utilization at their existing facility; similar provisions apply in other sections of the Plan, but there are other standards that still must be met.

COMMENT: Sam Tolbert (22) requested that Standards 9-10 on II-73-74 be replaced by allowing each applicant for a new ASF to demonstrate its need and for DHEC to be able to approve new ASFs if the need is clearly proven.

STAFF RESPONSE: This is essentially the situation we had prior to these standards being incorporated into the 2004-2005 Plan. Staff does not recommend accepting this recommendation.

COMMENT: Spartanburg Regional (20) recommended that Standard 11 on II-74 be amended to make a distinction be made for ASFs that are joint ventures with Not-for-Profit hospitals.

COMMENT: Roper St. Francis (4) recommended that, because ASFs do not see the volume of indigent care that hospitals do, Standard 11 on II-74 be amended to replace "comparable to other health care facilities" with "comparable to other ambulatory surgery facilities in the service area."

STAFF RESPONSE: Staff disagrees with the Spartanburg Regional proposal. We do not make any distinctions in our standards as to whether a proposed facility is proprietary or Not-for-Profit and do not believe there should be differing standards for different types of ownership/management. Staff agrees with the Roper proposal, but since there are counties without existing ASFs for the CON staff to compare the applicant with, staff recommends the following:

> The applicant for a new ambulatory surgery facility must provide a written commitment that the facility will accept Medicare and Medicaid patients, and that un-reimbursed services for indigent and charity patients will be provided at a percentage which is comparable to **all other existing** ambulatory surgery facilities, **if any**, in the service area.

COMMENT: SCHA (12) proposed a new Standard 12 for page II-74:

> Because of the substantial growth of ASFs and the concern that ASFs are being proposed as a method of increasing reimbursement for procedures currently being performed in physician offices, preference will be given to new hospital owned ASFs or those joint-ventured with hospitals.

STAFF RESPONSE: Staff disagrees with this comment. The standards incorporated in the 2004-2005 Plan have slowed the growth of ASFs by lengthening the timeframe between which applications for new facilities can be considered. While CMS has added additional surgical procedures to the list for which ASFs can receive Medicare reimbursement, they have also scaled back their reimbursement to 65% of the hospital outpatient surgery department rate. If there are concerns that "ASFs are being proposed as a method of increasing reimbursement for procedures currently being performed in physician offices" then it is irrelevant whether an ASF is hospital-owned or not. It should be noted that there might be financial advantages for hospital-owned ASFs to give up their ASF license and become incorporated into the hospital's outpatient surgery reporting system, which may decrease the incentive for hospitals to establish ASFs. At least one hospital has already expressed interest in the concept. Approximately 20% of the ASFs in the state are either hospital-owned or part of a hospital joint venture.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

I. (2) EMERGENCY HOSPITAL SERVICES (II-81-82)

COMMENT: Spartanburg Regional (20) supports Standard 1 clarifying that a CON is required to establish a freestanding emergency service.

COMMENT: SCHA(12) proposed that Standard 2 on page II-81 be amended:

> All off-campus emergency services must be an extension of an existing hospital's emergency service **in the same county**. The hospital must have a license that is in good standing and must be in operation to support the off-campus emergency services.

COMMENT: Spartanburg Regional (20) and Georgetown (27) also supported the recommendation that the hospital and proposed freestanding emergency service be located in the same county.

COMMENT: Palmetto Health (19) advocated that these services should be evaluated based on community need rather than by county line divisions. Since there are counties without hospitals in the state, this limitation could prevent these residents from having their needs met.

COMMENT: Bon Secours St. Francis (24) stated that having emergency services conveniently located is a benefit to state residents and location issues should be decided on a case-by-case basis rather than by a rigid geographic rule. Hospitals regularly serve patients from beyond their home county, so patients will benefit if hospitals are allowed to locate these services wherever a need for them can be demonstrated.

STAFF RESPONSE: Staff is conflicted on this issue. According to DHEC Health Licensing, the following facilities are considered to be freestanding emergency services (along with their associated hospitals):

Moncks Corner Medical Center (Trident) – Moncks Corner, Dorchester County
Seacoast Medical Center (Loris) – Little River, Horry County
South Strand Ambulatory Care Center (Grand Strand) – Myrtle Beach, Horry County
Roper St. Francis Northwoods (RSF) – North Charleston, Charleston County

Currently, the only freestanding emergency service that is not in the same county as its associated hospital is the Moncks Corner Medical Center. We don't want to encourage "turf wars" by allowing competing hospitals in nearby counties to use these services to encroach on each other's market base. However, Saluda, McCormick, Berkeley, Calhoun and Lee Counties do not have hospitals. To make purely hypothetical examples, what if Self Memorial wanted to set up a freestanding ER in McCormick or Saluda, or if Tuomey or McLeod wanted to set up an ER in Bishopville? These proposals could be viewed as attempts to capture additional market share, but would also improve emergency health

care access for those without hospital services in their county. A CON could not be approved for these theoretical examples if the same-county requirement is implemented. In addition, reading this strictly would mean that the Regional Medical Center could not establish a freestanding service in Calhoun County because the hospital itself is located in Orangeburg County. It is conjecture that any of the above examples might ever be proposed. However, staff believes a blanket exclusion could potentially prevent the expansion of health care services to underserved patients, and therefore does not recommend adding the requirement that the freestanding service and sponsoring hospital both be located in the same county. Alternately, the Committee may wish to craft language that would restrict these facilities to the same county as their hospital unless they are proposing to provide these services in counties that do not have a hospital.

COMMENT: Grand Strand Regional (30), Summerville Medical Center (31), Trident Health System (32), and Colleton Medical Center (33) noted the expansion of urgent care centers. They disputed that allowing hospitals to construct new emergency departments close to existing hospital ERs will cure the problem of overutilization. They recommended that a standard from the 2004-2005 Plan be re-added to this Plan:

> The proposed freestanding emergency service must be located no closer than 30 miles travel time from an existing hospital emergency department or off-campus emergency service.

COMMENT: SCHA (12), Spartanburg Regional (20), and Georgetown (27) recommended that a similar version of the 2004-2005 Plan standard be incorporated:

> The proposed freestanding emergency service must be located no closer than 30 **minutes** ~~miles~~ travel time from an existing hospital emergency department or off-campus emergency service.

COMMENT: Palmetto Health (19) recommended not incorporating a travel time requirement because it could limit access to some residents.

COMMENT: Bon Secours St. Francis (24) opposed the imposition of any rigid geographic limit, whether it is mileage, driving time, or county boundaries. Because of traffic conditions in many parts of the state, it can take more than 30 minutes to only travel a few miles during certain times of the day.

STAFF RESPONSE: In the 2004-2005 Plan, we had a standard that required that freestanding facilities could not be built within 30 miles of an existing emergency service. During the public comment period on the 2006-2007 Draft Plan that was eventually abandoned, we received 2 recommendations to delete this standard. As a result, staff deleted the standard when drafting the 2008-2009 Plan and submitted it for public comment. Trident *et. al.* recommend re-inserting the previous standard verbatim. SCHA *et. al.* recommend adding back the old standard, but that we use travel time in minutes rather than miles as the measurement. Palmetto Health and Bon Secours recommended not establishing a time or distance requirement. As stated above, staff has

concerns about balancing hospital market share competition with increased access to emergency care. It should be noted that all 4 of the existing freestanding emergency services are within 30 minutes and/or miles of existing hospitals; 2 of the existing providers favored tightening the standard while another advocated the more liberal position on this issue. Staff believes that there could be locations where the need for such a facility may be justified but could not be approved if a specific travel time requirement was in place. As a purely hypothetical example, Lexington Medical Center has 70,000+ visits annually at their emergency department. If they wanted to set up a freestanding emergency service in the Town of Lexington to both better serve that growing area of the county and reduce pressure on its current ER, they would be prohibited from doing so because it is not far enough away from the hospital.

COMMENT: Should the 30-mile standard not be re-inserted into the Plan, Grand Strand Regional (30), Summerville Medical Center (31), Trident Health System (32), and Colleton Medical Center (33) recommended that Standard 4 on page II-82 be amended as follows:

> An off-campus emergency service must have written agreements with Emergency Medical Services providers and surrounding hospitals regarding serious medical problems, which the off-campus emergency service cannot handle. **For any case in which a patient is transferred from the off-campus emergency service, it must transfer the patient to the geographically closest hospital having the capacity to treat the patient.**

STAFF RESPONSE: Based on discussions with the DHEC Legal Staff, we do not recommend accepting this recommendation.

COMMENT: Roper (4), SCHA (12), and Spartanburg Regional (20) recommended that an additional standard be created:

> The applicant must demonstrate need for this service by documenting where the potential patients for this proposed service will come from and why they are not being adequately served by the existing services in the area.

STAFF RESPONSE: These are specific CON criteria that must be addressed by all applicants during the review process. However, since we have similar wording in other sections, staff is not opposed to adding this as a new Standard 6 on page II-82.

COMMENT: Palmetto Health (19) recommended that language be added that would give preference to a licensed hospital over an independent provider.

STAFF RESPONSE: Standard 2 requires a freestanding ER to be an extension of an existing hospital's emergency service. Since there is no provision for the establishment of a service not affiliated with an existing hospital, this suggestion is not needed.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

(2) COMMUNITY PSYCHIATRIC BEDS (II-84-89)

COMMENT: Sunnyside Healthcare Commons (9) and Chartwell Capital (11) commented on the lack of psychiatric beds in the Allendale/Beaufort/Hampton/Jasper service area. They propose allowing an existing provider with less than 30 beds to increase to 30 beds to achieve economies of scale, or to allow a new provider to be approved for up to 30 beds regardless of the bed need.

STAFF RESPONSE: No basis was provided for the 30-bed minimum size presented in the comment; it just parroted the number from the general hospital provision. Of the currently licensed providers, 9 of the 20 have less than 30 beds, so it does not appear that 30 beds is an absolute minimum to successfully run a psychiatric program. The bed need methodology currently proposed in the Draft Plan would allow for 147 additional psych beds statewide, including 22 additional beds in that particular service area. Staff does not recommend accepting this comment.

COMMENT: The South Carolina Department of Mental Health (35) noted that the acute services for adults are limited to the number of beds that can be staffed. Crisis programs provide an alternative and work best when acute psychiatric inpatient beds for short stays for stabilization are also available in the community. Then limited state resources can be used to treat the more complicated severely and persistently mentally ill who need prolonged hospitalization. The underutilization of beds not in the state system seems to be exacerbated by the lack of funding for indigent patients.

COMMENT: SCHA (12) commended DHEC and DMH for revising and adding back the Local Crisis Stabilization Beds section (II-84-86), but requested an inventory to make sure that providers are using the beds appropriately.

STAFF RESPONSE: The Local Crisis Stabilization Beds program is intended to stabilize emergency psychiatric patients that in years past would have been transported to DMH in Columbia. Because of some concerns about the program, we omitted reference to it in the Draft 2006-2007 Plan. During the public comment period on that Draft, we worked with various parties to re-write the description and standards for the program. These would have been incorporated into that Plan if it had gone forward; instead, they were added to the current Draft. We will work with DMH to develop an inventory of providers and utilization.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

(3) RTF FOR CHILDREN AND ADOLESCENTS (II-90-93)

COMMENT: The South Carolina Department of Social Services (36) recommended that the finalization of this section of the Plan be delayed. Because of Health and Human Services Budget Proviso 8.35, high management group homes may seek licensure as an RTF without having to go through the CON process. Since a number of group homes have given notice of their intent to seek RTF licensure, these conversions could potentially double the number of RTF beds in the state, far more than allowed in the Draft bed need methodology.

COMMENT: DHHS (37) also noted that the proviso was inconsistent with a federal waiver and 5 year funding they recently received to establish community-based services to youth who meet this level of care. Their research indicates that community-based services are more effective than institutional services. This proviso is also inconsistent with the "Guiding Principles" that have been developed in collaboration with the various state agencies that care for children with emotional and/or behavioral problems.

STAFF RESPONSE: The CON program has no control over this proviso, which allows these group homes to become licensed as RTFs without a CON and regardless of the projected need for these beds. However, if a currently licensed RTF wanted to expand it would have to comply with the projected bed need. The current bed need methodology has been in place since 1999. We are projecting a need for 404 beds in the Draft and have 376 existing beds. However, we have already issued CON exemptions to 8 facilities for a total of 401 new RTF beds and have an additional 4 applications pending. The exemptions are valid for 18 months rather than the normal 6 months, so it could be another year before these facilities either are licensed or allow the exemption to lapse. Even if not all facilities follow through with the conversion we could still potentially have far more licensed beds than are projected as needed, which renders the bed need calculations moot. Staff acknowledges that this proviso is inconsistent with prior agency collaborative efforts but it is beyond our control. Since we will not know what the final impact of this proviso will be for some time to come, we don't want the entire Plan held up because of this issue. Since a numerical projection is apparently no longer appropriate, staff recommends that the Committee consider amending this section by eliminating the bed need methodology on pages II-91 and II-92. Instead, staff suggests incorporating the following alternative standards:

(1) Except in the case of high management group homes that received exemption from CON through Health and Human Services Budget Proviso 8.35, the establishment or expansion of an RTF requires a CON.

(2) The applicant must document the need for the expansion of or the addition of an RTF, based on the most current utilization data available. The existing resources must be considered and documentation presented as to why these resources are not adequate to meet the needs of the community.

(3) For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. For the expansion of an existing facility, the applicant must provide patient origin information on the current facility.

(4) The applicant must document the potential impact that the proposed new RTF or expansion will have upon the existing service providers and referral patterns.

(5) The applicant must provide a written commitment that the facility will provide services for indigent and charity patients at a percentage that is comparable to other health care facilities in the service area.

(6) The applicant agrees in writing to provide utilization data on the operation of the facility to the Department.

COMMENT: The South Carolina Department of Social Services (36) noted that some of the existing RTFs are primarily serving patients from outside South Carolina, which artificially skews the utilization of these beds. They recommend that some consideration be given to this issue.

STAFF COMMENT: We do not currently collect patient origin data for RTFs. Staff is willing to conduct a special survey or amend the 2008 Joint Annual Report to collect baseline data for analysis.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

(4) ALCOHOL AND DRUG ABUSE FACILITIES (II-94-102)

COMMENT: Upstate South Carolina Recovery Center (25) requested that a provision be made in the Plan to allow the bed needs of different planning areas to be combined in order to create a regional substance abuse disorder treatment facility. They want to have both inpatient and residential beds, but do not know the precise mix of these beds.

STAFF RESPONSE: Inpatient Treatment Facility beds (pages II-98-101) require CON review while Residential Treatment Program Facility beds (II-97) do not. So, only a part of their proposal is contingent upon making this amendment to the Plan. Inpatient treatment facility utilization has steadily decreased; the non-state facilities had an overall utilization rate of 36.1% in 2006. Only 8 of the 13 service areas in the Plan even have programs. Staff presumes the commenter is considering combining the Greenville and Spartanburg service areas. There is a need for additional beds in both service areas, but since there have been no licensed facilities in the Spartanburg service area since approximately 1987, there appears to be no local interest in establishing such services. The only concern about a provision allowing the creation of a regional treatment center is whether it could allow the applicant to gain a competitive advantage on the existing provider(s). In this example, an applicant could take the 11 beds needed in the Greenville area and the 16 from the Spartanburg area to create a 27 bed facility, whereas the existing provider in Greenville could only add 11 beds should it desire to add beds. However, since this comment could be applicable for more than a single service area, and it is only a request for a mechanism to allow such a proposal to be considered, staff recommends the following new paragraph be added to page II-100 after the existing third paragraph spelling out when additional inpatient beds could be considered:

> The establishment of a regional treatment center that serves more than a single service area may be proposed in order to improve access to care for patients in service areas that do not currently have such services available. Such a proposed center would be allowed to combine the bed need for a service area without existing services with another service area providing this other service area shows a need for additional beds. The applicant must document with patient origin data the historical utilization of the residents in the service area that is to be combined, or why it is in the best interest of these residents for their projected bed need to be used to used to form a regional treatment facility.

COMMENT: SCDMH (35) noted that their inpatient substance abuse treatment program for adults is primarily a residential facility, providing a structured therapeutic environment for a longer period of time than an acute program.

STAFF RESPONSE: Staff agrees that DMH patients have different needs than acute program patients. Therefore, the state facilities' utilization is maintained separately and is not included in the projections of need for acute programs.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

(5) REHABILITATION (II-103-105)

COMMENT: Sunnyside Healthcare Commons (9) and Chartwell Capital (11) commented on the availability of rehab beds statewide. They propose allowing an existing provider with less than 30 beds to increase to 30 beds to achieve economies of scale, or to allow a new provider to be approved for up to 30 beds regardless of the projected bed need.

STAFF RESPONSE: There is a reasonable argument for establishing a minimum bed compliment for rehabilitation because of the required investments in technology and staffing. However, this is a somewhat uncertain time for rehab services because of reimbursement changes by CMS that may impact future utilization. The bed need methodology proposed in the Draft Plan would allow for 87 additional rehab beds statewide. Staff recommends deferring acting on this proposal until the next Plan: 1) to give all affected parties an opportunity for input as to whether such a standard is necessary, and 2) by that point in time we should have a clearer picture of the future of rehab services.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

A. NURSING HOMES (II-108-114)

COMMENT: DHHS (37) noted that the more recent terminology used by CMS is "nursing facility" rather than "nursing home" and "resident" rather than "patient."

STAFF RESPONSE: Staff recommends making these replacements throughout the entire Plan as appropriate.

COMMENT: DHHS (37) stated that they are now funding more persons in Medicaid-sponsored long term care in community settings rather than in nursing facilities. They provided updated information on the additional options available through their programs.

STAFF RESPONSE: Staff recommends that the following wording be added to page II-107 following (d) (4) and prior to the discussion of the bed need methodology:

> DHHS operates 3 home and community-based Medicaid waiver programs through its Community Long Term Care (CLTC) network. These programs provide alternatives to institutional care for participants who are eligible to receive an institutional level of long term care but prefer to receive their care in the home and/or in a community setting. Community Choices is funded for 12,000 slots for FY 07-08; the other waivers serve 1,000 persons with HIV disease and approximately 30 adults who are dependent upon mechanical ventilation. The PACE program is jointly funded by Medicare and provides primary and long-term care services to participants' age 55 and older that meet the State's nursing facility level of care. The Palmetto SeniorCare (PSC) Program operates 5 PACE Centers in Richland and Lexington Counties and served 440 participants during FY 2007. A second PACE site began operation in March 2008 operated by The Oaks CCRC in Orangeburg. DHHS is also participating in a federal initiative called Money Follows the Person, which allows people who have been in a nursing facility for at least 6 months to transition back to the community.

COMMENT: DHHS (37) recommended that the 2nd statement at the bottom of page II-107 should be updated.

STAFF RESPONSE: Staff recommends that the following wording be substituted for this section:

> The CLTC program provides the following community-based services for participants who prefer to receive care in the community rather than institutional care:
>
> a. Personal Care;
> b. Environmental Modifications;

c. Home Delivered Meals;
d. Adult Day Health Care (ADHE);
e. Respite Care;
f. Personal Emergency Response System (PERS);
g. Durable Medical Equipment;
h. Nursing Services; and
i. Case Management

COMMENT: DHHS (37) also provided information on Medicaid waiver programs operated by the Department of Disabilities and Special Needs (DDSN).

STAFF RESPONSE: Staff recommends that the following wording be added to the end of the 2nd paragraph on page II-113:

> DDSN also operates three home and community-based Medicaid waiver programs for the following target groups: Mental Retardation and Related Disabilities, Head and Spinal Cord Injuries, and Pervasive Developmental Disorders.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

C. HOSPICE FACILITIES AND HOSPICE PROGRAMS (II-115)

COMMENT: DHHS (37) proposed that hospice should be put under CON because of the rapid growth and rising expenditures for this service.

STAFF RESPONSE: This would require amending the CON law, since an outpatient hospice is not defined as a health care facility or service under current law. Inpatient hospice requires a CON because it is licensed as a health care facility.

E. HOME HEALTH AGENCIES (II-118-129)

COMMENT: DHHS (37) supports the Plan's interest in increasing access and availability for home health services to the pediatric population.

COMMENT: The South Carolina Home Care Association (34) supports the CON process for home health because it prevents an overgrowth of agencies. However, they believe the current language is not adequate for review of a pediatric home health agency (Standard 7 on page II-120) and proposed the following amendments:

> Because of the limited number of home health providers available to treat children 14 years or younger, an exception to the above criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing **intermittent** ~~the service of pediatric~~ home health skilled nursing services **to patients 14 years or younger. A Certificate of Need application will be required for each county in which** ~~Only one Certificate of Need application will be required for~~ an agency that proposes to provide this specialized service to pediatric patients **14 years or younger** ~~in multiple counties~~. The applicant must document that no other agency offers this service in the county of application, and the agency will limit such services to the pediatric population **14 years or younger. The agency must be Medicare-certified or accredited through The Joint Commission, the Community Health Accreditation Program, or the Accreditation Commission for Health Care**. The license for the agency will be restricted to serving children 14 years or younger and will ensure access to necessary and appropriate **intermittent** home health **skilled nursing** services **to patients 14 years or younger**. Any such approved agency will not be counted in the county need projections.

STAFF RESPONSE: The proposal to require a separate CON for each county to be served is not consistent with previous Department policy in reviewing applications for a limited service [**Note**: Matria filed 2 CONs to provide OB monitoring in every county statewide; see page II-126]. After discussions with DHEC Legal staff, it was determined that we cannot mandate that a facility seek federal reimbursement or membership in a voluntary association that is not mandated by law as a prerequisite for receiving a CON [**Note**: This differs from the determination and subsequent staff recommendation on

LTCH's because Medicare certification is a mandatory federal requirement in order to be classified as an LTCH]. Staff proposes the following revision of Standard 7 on page II-120:

> Because of the limited number of home health providers available to treat children 14 years or younger, an exception to the above criteria may be made for a CON for a Home Health Agency restricted to **providing intermittent** ~~the service of pediatric~~ home health skilled nursing **services to patients 14 years or younger**. Only one CON application will be required for an agency that proposes to provide this specialized service to pediatric patients in multiple counties**; the applicant must specify which counties they propose to provide these services in**. The applicant must document that no other agency offers this service in the county of application, and the agency will limit such services to the pediatric population **14 years or younger**. The license for the agency will be restricted to serving children 14 years or younger and will ensure access to necessary and appropriate **intermittent** home health **skilled nursing** services **to these patients**. Any such approved agency will not be counted in the county inventories for need projection **purposes**.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

CHAPTER III

REGION III NARRATIVE (III-24)

COMMENT: Tuomey Healthcare (2) noted that Shaw AFB no longer operates inpatient facilities. They asked that the reference to the Shaw AFB hospital be deleted because these patients are now treated at Tuomey.

STAFF RESPONSE: This reference should be deleted.